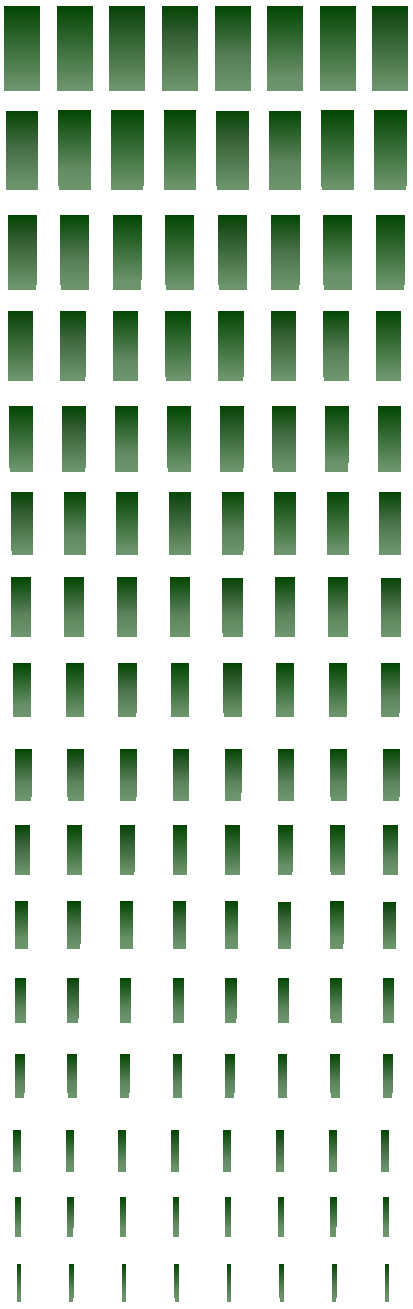

Washington State Institutional Review Board Procedures Manual

April 2004

Washington State Department of Social and Health Services
Management Services Administration
Research and Data Analysis Division
Human Research Review Section

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD
PROCEDURES MANUAL

April 1, 2004

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Table of Contents

WASHINGTON STATE INSTITUTIONAL REVIEW BOARD
PROCEDURES MANUAL

1.0 PURPOSE AND AUTHORITY OF THE REVIEW BOARD

1.1 Purpose of the Review Board

The purpose of the Washington State Institutional Review Board (WSIRB) is to protect the rights and welfare of individuals who participate in research under the jurisdiction of three Washington State Agencies: the Department of Social and Health Services (DSHS), the Department of Health (DOH), and the Department of Labor and Industries (L&I). In fulfillment of these State Agencies' Federalwide Assurances with 45 CFR Part 46 and the *Washington State Agency Policy on the Protection of Human Research Subjects,* the Review Board ensures for each research project reviewed that the rights and welfare of participants are adequately protected; that the risks to individuals are minimized, are not unreasonable, and are outweighed by the potential benefits to the individual or by the knowledge to be gained; and that the proposed project design and methods are adequate in light of the stated project purposes.

1.2 Authority of the Review Board

The Washington State Institutional Review Board (WSIRB or the Review Board) is established under the general statutory authority of the Secretary of the Washington State Department of Social and Health Services. (RCW 43.20A.050 and RCW 43.20A.110). The WSIRB is registered with the federal Office of Human Research Protections (OHRP) in the Department of Health and Human Services; the three state agencies, DSHS, DOH, and L&I, have Federalwide Assurances (FWAs) on file at OHRP. All three state agencies have adopted the *Washington State Agency Policy on Protection of Human Research Subjects.*

The operation of the WSIRB is subject to the human subjects protection rules, policies, and guidelines contained in the following documents:

- Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, as revised June 18, 1991
- Title 45, Code of Federal Regulations, Part 164, Privacy Rule – Security and Privacy
- The Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979
- Chapter 42.48, Revised Code of Washington, Release of Records for Research

- Chapter 70.02, Revised Code of Washington, Medical Records – Health Care Information Access and Disclosure

- Chapter 388-04, Washington Administrative Code, Protection of Human Research Subjects

- DSHS Administrative Policy 12.01, Human Research Review

- DOH Policy/Procedure 03.001, Human Research Review

- L&I Policy 9.43, Human Research Review Process

As provided in these documents, the Washington State Institutional Review Board has the following powers:

- Research in the jurisdiction of these state agencies may not proceed until the protocol has been reviewed and approved by the Review Board[1]. In the course of its deliberations, the Review Board may approve proposals, disapprove proposals, or defer final approval until review issues have been resolved.

- The Review Board may prescribe scientific and ethical restrictions or conditions under which a project may be conducted, require substantive changes in project plans, and determine the nature and frequency of interim review procedures necessary to ensure continued acceptable conduct of the project.

- Negative Review Board decisions (disapprovals, restrictions, or approval conditions) are binding, are not subject to administrative override, and may be rescinded only by action of the Board. Projects approved by the Board are subject to further review, disapproval, or restrictions by departmental officials.

- The Review Board may suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to participants.

[1] At the discretion of the Human Protections Administrator of these Washington State Agencies, research in the jurisdiction of that agency may be forwarded for review by an alternate institutional review board designated on that agency's Federalwide Assurance. Reliance on the IRB of another FWA institution requires documentation on an IRB Authorization Agreement signed by the Institutional Official of the respective FWA institutions and filed with the DSHS Human Research Review Section.

2.0 MANAGEMENT AND SUPPORT OF THE REVIEW BOARD

2.1 Human Research Review Section

The Human Research Review Section (HRRS) in the Department of Social and Health Services, Research and Data Analysis Division, provides administrative and staff support to the Washington State Institutional Review Board, and is responsible for the receipt, processing, and disposition of all research proposals that require review by the Review Board.

The Review Section staff:

- Provide consultation to researchers;
- Receive and process research proposals that require review;
- Communicate Review Board decisions to researchers;
- Request progress reports for continuation review;
- Advise researchers and agency program managers regarding human research review policies and procedures;
- Maintain and update the Review Section's website which contains the State Agency and Review Board policies and procedures, application forms, and other information related to the review process;
- Facilitate required training and provide training resources on human subjects protection to researchers and Review Board members.

2.2 HRRS Manager

The HRRS Manager is responsible for implementing and directing the operations of the Washington State Institutional Review Board and for ensuring compliance with applicable federal and state laws and regulations and departmental policies and procedures. The HRRS Manager serves as the Executive Secretary (ES) and a permanent voting member of the WSIRB. As the Human Protections Administrator for the Department of Social and Health Services, the HRRS Manager also is responsible for the human subjects protection program in that state agency, and provides technical consultation, educational resources and guidance to the Human Protection Administrators for the Department of Health and the Department of Labor and Industries. In these multiple roles, the HRRS Manager has the following responsibilities:

As the HRRS Manager:

- Assigns review workload to HRRS staff and WSIRB members and provides technical consultation to WSIRB members during review of research proposals;

- Ensures that Review Board decisions are enforced, monitors ongoing human research projects under the review by the Review Board;

- Maintains the credibility of the review process through constructive contacts with investigators, agency managers and administrators;

- Provides professional liaison with federal and state agencies;

- Coordinates the WSIRB human research review process with the University of Washington Human Subject's Division, Fred Hutchinson Cancer Research Center Institutional Review Office and other IRBs;

- Plans, develops, and proposes policies and procedures concerning the review and approval of human subjects research and the confidentiality of personal records;

- Hires and supervises HRRS staff; manages HRRS fiscal and computer resources to optimize research review objectives; approves travel and per diem for staff and Review Board members.

As the WSIRB Executive Secretary:

- Provides technical support, training, and guidance to the WSIRB Chairs; assists the WSIRB Chairs to efficiently and effectively run the WSIRB meetings;

- Reviews research proposals for compliance with scientific, ethical, and legal standards for conducting research;

- Consults with investigators and primary reviewers regarding scientific, legal, ethical, and programmatic implications of proposed research design and protocols.

- With delegated authority from the WSIRB Chairs, conducts expedited reviews of new proposals with at least one other member of the Review Board, and conducts expedited reviews of "minor changes in previously approved research during the period for which approval is authorized," with or without participation of another member of the Review Board, at his or her discretion.

As the DSHS Human Protections Administrator:

- Implements and maintains the human subjects protection program in the Department of Social and Health Services;

- Provides technical consultation and support for the maintenance of the human subjects protection programs in the Department of Health and the Department of Labor and Industries and in other state agencies;

- Determines which DSHS activities constitute research that is subject to WSIRB review and approval;

- Advises researchers and the Human Protections Administrators for the Department of Health and the Department of Labor and Industries regarding which activities are subject to IRB review and approval.

2.3 HRRS Review Coordinator

In consultation with the HRRS Manager, the HRRS Review Coordinator provides professional staff support to the Review Board. The HRRS Review Coordinator also serves as the Associate Executive Secretary (AES) and is a permanent voting member of the WSIRB. The HRRS Review Coordinator/WSIRB Associate Executive Secretary has the following duties:

- Reviews research proposals for compliance with scientific, ethical, and legal standards for conducting research.

- Consults with investigators and primary reviewers regarding scientific, legal, ethical, and programmatic implications of proposed research design and protocols.

- With delegated authority from the WSIRB Chairs, conducts expedited reviews of new proposals with at least one other member of the Review Board, and conducts expedited reviews of "minor changes in previously approved research during the period for which approval is authorized," with or without participation of another member of the Review Board, at his or her discretion.

- Prepares minutes of Review Board meetings based on correspondence to investigators and meeting notes.

- Conducts outreach and educational activities with research professionals and program managers in three state agencies.

- Develops and conducts workshops for researchers on the requirements for research involving human subjects.

- Conducts site visits and audits research procedures to ensure compliance with Review Board requirements for conducting approved research and to investigate suspected or reported noncompliance.

- Analyzes policy manuals, application forms, instructions to researchers, review worksheets, etc., to identify and recommend ways to improve the quality of reviews of research proposals and to accommodate increasing workloads.

2.4 HRRS Administrative Assistant/Training Coordinator

The HRRS Administrative Assistant/Training Coordinator provides administrative and technical staff support to the Review Board and has the following duties:

- Coordinates continuing review of active research by reviewing project files at least annually to ensure compliance with Board-approved methods and procedures.

- Organizes and coordinates the Review Board workload of active research projects using the HRRS Lotus Notes Tracking Database and maintaining project files.

- Screens and directs all telephone inquiries and mail.

- Arranges for meeting rooms and travel arrangements.

- Prepares meeting agendas, meeting minutes, and distributes Review Board materials to Review Board members.

- Works with the web coordinator to maintain the HRRS website and ensure that information on the website is current.

- Facilitates and monitors required training in the protection of human subjects for HRRS staff, Review Board members, and researchers.

3.0 REVIEW BOARD ORGANIZATION AND MEMBERSHIP

3.1 Composition of the Review Boards

The Washington State Institutional Review Board consists of two separate, parallel Review Boards: Board A and Board B. Each Review Board has 14 to 16 members, with varying backgrounds to promote complete and adequate review of research activities conducted within the jurisdiction of the three Washington State Agencies, DSHS, DOH, and L&I. The Review Board is sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of research participants.

In addition to possessing the professional competence necessary to review specific research activities, the Review Board is qualified to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The Review Board therefore includes persons knowledgeable in these areas. The Review Board also includes persons who are knowledgeable about and experienced in working with vulnerable populations such as children, prisoners, pregnant women, and physically or mentally disabled persons.

Each Review Board includes several members whose primary concerns are in scientific areas, and at least one member whose primary concerns are in nonscientific areas. Each Review Board includes several members who are not otherwise affiliated with Washington State agencies, and who are not part of the immediate family of a person who is affiliated with the Washington State agencies. Each Review Board has at least two members who are physicians licensed to prescribe drugs in the State of Washington. Every effort is made to include members who mirror the ethnic and racial composition of subjects who volunteer for research under review. The Review Board maintains at least one ad hoc member who serves as a prisoner representative during the review of research involving prisoners.

3.2 Board Members

3.2.1 Appointment

Recommendations for Review Board membership are solicited by the Executive Secretary from departmental administrators, Board members, and non-departmental professional and human service agencies and organizations. Candidates for Review Board membership are submitted for consideration and formal appointment by the Secretaries of DSHS, DOH, or L&I. The Secretary of DSHS appoints candidates to the Board who are DSHS employees or who are not employed by DSHS, DOH, or L&I. The Secretary of DOH appoints candidates to the Board who are

DOH employees, and the Director of L&I appoints candidates who are employees of L&I. Board members who are not employees of a state agency are appointed as official volunteers with DSHS. Volunteer status provides members with the services of the Office of the Attorney General in the event that legal representation is required as a result of participation in Review Board business.

3.2.2 Length of Service

Board members serve a term of one year upon their first appointment. To assure continuity of Board operations, members may be appointed for terms of one, two, or three years following expiration of their first term. Members who exceed ten years of service on the Review Board are recognized as Distinguished Members.

3.2.3 Duties

Members of the Washington State Institutional Review Board are expected to contribute time necessary to complete Review Board business. The Review Board meets eight times per year at alternating six and seven week intervals. Board members are expected to attend at least five meetings per year. Depending on the workload, members spend approximately four to eight hours reviewing proposals prior to a Board meeting. DSHS, DOH, and L&I employees appointed to the Board are authorized by their agency to set aside time from their regular duties for review preparation, meeting attendance, and other Board business.

During the review of research proposals, members do not participate as representatives of the agency or organization with which they may be affiliated or employed. Rather, each member brings to the review task his/her own expertise, principles, and points of view based on his/her own unique experiences and background. Members are expected to indicate if they have a conflict of interest with any research proposal under consideration.

During the review of each research proposal under consideration, whether the review is conducted through the expedited or full-Board review process, the duties of Board members include, but are not limited to, determining that:

- Risks to subjects are minimized, and are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

- Taking into account the purposes of the research and the setting in which the research will be conducted, selection of subjects is equitable.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and that it is appropriately documented, in accordance with and to the extent required by state and federal statute and regulation.

- Approval of a waiver of consent or waiver of authorization is extended only when all application criteria in state and federal statute and regulation have been satisfied.

- When appropriate, adequate plans are in place to monitor the data collected to ensure the safety of subjects.

- Adequate plans are in place to protect the privacy of subjects and to maintain the confidentiality of data.

- Additional safeguards are in place to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically and/or educationally disadvantaged persons.

3.2.4 Severance

Review Board members may resign from the Review Board upon written notification to the Executive Secretary.

If a member fails to attend more than three consecutive meetings, violates the confidentiality rules specified under Section 4.4 of this document, or otherwise behaves in a manner that is inconsistent with the mission of the Review Board, the Executive Secretary may recommend the member's severance from Board membership at a meeting of the full Board. The matter is decided by a vote of the Board.

3.3 Chairperson

3.3.1 Appointment

Candidates under consideration for the position of Chairperson must have been a member of the Review Board for not less than one year and must be affiliated with DSHS, DOH, or L&I. Affiliation is defined as being an employee of, or permanent consultant with, one of these agencies. Staff of the Washington Institute for Mental Illness Research and Training are considered to be affiliated with DSHS.

Candidates for Chair of the Review Board are selected by the Executive Secretary and the outgoing Chairperson based on demonstrated commitment to the mission of the Review Board and on the ability to

command the respect of members of the Review Board. Candidates are also sought on the basis of their ability to run meetings in an efficient and effective manner, and to provide leadership and facilitate problem solving during meeting deliberations. The Review Board Chair is appointed by the Secretary of the Department of Social and Health Services based on the recommendation of the Executive Secretary.

3.3.2 Length of Service

The Chairperson is appointed to an initial term of one year. Upon successful completion of an initial term, the Executive Secretary will invite the Chair to accept reappointment for up to two consecutive terms of two years each. The total time a person may serve as Chair of the Review Board is five years. At the conclusion of a five year term as Chair of the Review Board, a Chairperson may elect to remain as a member of the Board.

3.3.3 Duties

In addition to the duties of a member, the Chairperson's duties include, but are not limited to, the following:

- Conduct Board meetings following a prepared timed agenda in accord with the *WSIRB Rules of Order.*

- Direct Board deliberations to focus essential review concerns; probe Board consensus on critical review issues by eliciting individual votes; lead the Board to develop clear disposition instructions for correspondence to investigators by the Executive Secretary and Associate Executive Secretary.

- Serve as a voting member for the purpose of 1) breaking a tie vote; 2) satisfying quorum requirements if meeting attendance falls short by one Board member; and 3) participating in the expedited review of proposals.

- Share with the Executive Secretary in assuring Review Board compliance with *Washington State Agency Policy on Protection of Human Research Subjects* and *WSIRB Procedures Manual*.

- Share with the Executive Secretary in making recommendations for appointment of new Board members and in selecting candidates for Chairperson.

- Share with the Executive Secretary in representing the Review Board administratively within the three state agencies.

- Sign meeting minutes prepared by the Associate Executive Secretary.

The Review Board Chairperson delegates to the Executive Secretary and Associate Executive Secretary authority to carry out the following duties (per 45 CFR 46.110):

- Conducting expedited reviews of new proposals with at least one other member of the Review Board.

- Conducting expedited reviews of minor changes in previously approved research during the period for which approval is authorized, with or without participation of another member of the Review Board at his or her discretion.

- Signing all official Review Board correspondence.

3.3.4 Appointment of Chair Pro Tem

If unable to attend a meeting, a Chairperson should inform the Executive Secretary, if possible, at least three weeks prior to the scheduled meeting date. Under this circumstance, the Executive Secretary has the authority to appoint another qualified member of the Review Board to serve as Chair Pro Tem for that meeting.

3.3.5 Severance

The Chairperson may resign from the duties of the Chair upon written notification to the Executive Secretary.

If a Chairperson fails to attend more than two consecutive meetings, violates the confidentiality rules specified under Sec. 4.4 of this document, or otherwise behaves in a manner that is inconsistent with the mission of the Review Board, the Executive Secretary may recommend the Chair's severance from Board membership at a meeting of the full Board. The matter is decided by a vote of the Board.

3.4 Use of Consultants

If a proposal requires expertise beyond those represented on the Review Board, the Chairperson and/or the Executive Secretary may seek verbal advice or written consultation from outside professionals. When consultation is obtained, however, the Board remains responsible for independently determining the scientific and ethical acceptability of the proposal. Consultation with outside experts shall preserve the anonymity of the researcher, or if this is not possible, shall be conducted in a confidential manner. Consultants may participate in the discussion of a proposal at the meeting, but may not be present during or participate in the voting process. Copies of the consultant's viewpoint are distributed to all Board members prior to the meeting.

3.5 Board Member Education/Training

Under the *Washington State Agency Policy on Protection of Human Research Subjects*, members of the Washington State Institutional Review Board are required to complete training in the protection of human subjects. Review Board members must complete the training requirement within three months of their initial appointment to the WSIRB. Retraining is required every three years.

Review Board members may satisfy this education and training requirement through any of the following options:

- Attending a tutorial session offered quarterly by the University of Washington and the Fred Hutchinson Cancer Research Center. Class schedules, and registration information are available on the University of Washington website: http://dept.washington.edu/hsd/INFO/train.htm.

- Completing the web CITI Training in the Protection of Human Subjects on the University of Miami website: http://www.miami.edu/bb/citireg/. Members must complete all required modules and the quizzes for these modules, and review the *Washington State Government Agencies Institutional Page* and links, to receive credit for training. The required modules are listed under *Instructional Requirements for Washington State Government Agencies on the Review Boards website*.

- By attending the annual IRB Regional Educational Conference sponsored by the University of Washington, Fred Hutchinson Cancer Research Center, Children's Hospital and Regional Medical Center and other Western Washington institutions.

The cost of completing required Board member training is included in the HRRS budget. Links to the web-based training listed above may be accessed through the HRRS website at http://www1.dshs.wa.gov/rda/hrrs. A list of individuals who completed the required training, along with the date of their training, is maintained on the HRRS website.

In addition to the required member training, the Executive Secretary's Report at the beginning of each Board meeting includes timely information on subjects of relevance to the work of the Review Board. Topics covered include regulatory updates, state legislative and policy developments, and current or future WSIRB quality improvement initiatives.

Educational resources supplied to members include a subscription to *IRB: Ethics and Human Research.* This journal, published six times a year by The Hastings Center, includes articles written by recognized experts in the protection of human subjects on cutting edge topics of interest in the field. When they are appointed to the Review Board, members also receive a *Board Member Handbook* which includes resource materials needed for reviewing research proposals.

3.6 Reimbursement

DSHS, DOH, and L&I employees appointed to the Review Board receive mileage and sustenance reimbursement (if applicable) from their own organizational units. Members who are not DSHS, DOH, or L&I employees are reimbursed from an HRRS account for mileage to and from meetings, and receive sustenance reimbursement at the standard state rate.

3.7 Conflict of Interest

No Review Board member may participate in the Review Board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Review Board. Conflicts of interest may arise for either financial or personal reasons. Prior to discussion of research proposals, the Chair shall ask Review Board members to disclose any potential conflicts of interest they may have to the Review Board, and this shall be noted in the meeting minutes.

Members who have a significant conflict of interest (e.g., being the PI or Co-PI, a contributor to the design of the research, or a member of the research staff) must recuse themselves from consideration of the research proposal. Members who recuse themselves must leave the meeting room during discussion of and voting on the research proposal, and are not counted in the quorum for consideration of that agenda item. Members who have a less significant conflict of interest (e.g., the proposal was developed by a researcher in the same organizational unit, but the member did not make a direct contribution to the research) may remain in the room during consideration of the proposal, but should not participate in the discussion except to answer questions, and must abstain from the vote. Members who abstain from voting are counted in the quorum for consideration of that item.

The Chair of the Review Board shall be the final arbitrator regarding whether a member's conflict is significant enough to require recusal from consideration of an agenda item. If the Chair has a conflict of interest, the Executive Secretary shall decide if the conflict is significant enough to require recusal. If recusal of the Chair is required, the Executive Secretary shall chair the meeting until the Chair is able to return to the meeting.

3.8 Liability Coverage

State law (RCW 4.92.060) provides that state officers, employees, and volunteers may request representation by the Attorney General in any action or proceeding for damages in which the officer, employee, or volunteer has been named a defendant. Representation from the Office of the Attorney General applies to legal claims arising from acts or omissions which occurred while performing, or in good faith purporting to perform, official duties.

Representation from the Office of the Attorney General is available to all Board members who are state employees or volunteers of state agencies for their acts or omissions, if such acts/omissions are determined to be in good faith and within the scope of their official duties and responsibilities as member of the Washington State Institutional Review Board. Where representation from the Office of the Attorney General is provided, Board members are protected from judgments against the State of Washington.

To provide representation from the Office of the Attorney General, Review Board members who are not state agency employees are officially appointed as volunteers of the Department of Social and Health Services for purposes of performing their official Review Board duties.

4.0 REVIEW BOARD OPERATIONS

4.1 Meeting Schedule and Venue

The Review Board meets on Thursdays eight times per year at six to seven week intervals. Review Board A meets in the afternoon and Review Board B meets in the morning. To accommodate Board members who live in Seattle as well as in the Tacoma and Olympia areas, meetings generally are held at the Tacoma Rhodes Center in downtown Tacoma. The Board meeting typically lasts from three to four hours. A calendar of Board meetings is posted on the WSIRB website.

4.2 Distribution of Materials

Review materials and information are mailed to all Board members approximately one week before each scheduled meeting. Review materials distributed prior to each meeting include:

- A Detailed and a Timed Meeting Agenda
- Minutes from the previous Review Board meeting
- Review Worksheets and Subpart B, C, and D Worksheets, as applicable to research under review
- *Research Applications* for full-Board review
- *Progress Reports* for full-Board continuation review
- *Requests for Study Amendments* for full-Board review
- *Project Application Summary (Form A)* and initial correspondence to the investigator for applications eligible for expedited review
- *Progress Reports* for expedited continuation review
- *Requests for Study Amendments* and initial correspondence to the investigator for expedited review
- *Reports of Adverse Events and/or Unanticipated Problems*
- Suspensions and other Board actions
- Report on final study approvals
- Report on canceled and completed projects
- Current issue of *IRB: Ethics and Human Research*

Materials pertaining to Review Board actions taken under expedited review authority are distributed to all Board members for informational purposes. Either at or before the meeting, Review Board members may ask questions, raise issues, and/or ask for full-Board consideration regarding any actions taken under expedited review authority

4.3 WSIRB Rules of Order

WSIRB Rules of Order, adapted from *Robert's Rules in Plain English,* by Doris P. Zimmerman, are used as a guide for conducting business during full-Board meetings. The *WSIRB Rules of Order* are intended to provide a mechanism to keep Board meeting deliberations focused on relevant topics, to promote efficient use of meeting time, and to allow all members to participate in the review process, while not unduly inhibiting discussion and/or debate among Board members. The Chairperson has the authority to implement the *WSIRB Rules of Order* to the extent that he/she believes this intent is being met, or to suspend the *WSIRB Rules of Order* if he/she believes they are acting as an impediment to running the meeting in an efficient and effective manner. The *WSIRB Rules of Order* are also used to settle disagreements about procedural matters.

4.3.1 Basic Rules

A. All members are equal and their rights are equal. Those rights are:
   - To attend meetings
   - To make motions
   - To speak in debate
   - To vote

B. A quorum must be present to do business:
   - A quorum is a simple majority of IRB members; at least one member whose primary concerns are in non-scientific areas must be present.
   - Members who do not vote (abstain) are counted toward the quorum.
   - Members who recuse themselves from consideration of a proposal due to conflict of interest must leave the room and are not counted in the quorum.

C. The majority rules:
   - A majority means the majority of members present.
   - The minority has the right to be heard.
   - Once a decision has been made by the majority, the minority must then respect and abide by the decision.

D. Silence is consent:
- Members who do not vote (abstain) agree to go along with the decision of the majority by their silence.

E. A two-thirds vote is required whenever:
- The rights of members are limited or taken away.
- Something that has already been decided is being changed.

F. One question at a time and one speaker at a time:
- No motion is in order which does not directly relate to the question under consideration.
- Once a member has been recognized by the Chair, he/she has the floor and may not be interrupted.

G. Debatable motions must receive full debate:
- Debatable motions may not be voted on as long as members wish to debate it.
- Exception: debate can be suspended by a two-thirds vote of members present.

4.3.2 Duties of Chairperson during Board Meetings

A. Arrive on time and start on time.

B. Follow the timed agenda and keep on schedule.

C. Be in control of the floor:
- "Assign" the floor by recognizing members who wish to speak.
- Remind those who interrupt that the floor has been assigned to another.
- Discourage private conversations during the meeting.
- Be impartial when calling on members to speak.

D. Direct deliberations to focus on essential review concerns.

E. Facilitate consensus on critical issues by eliciting individual votes.

F. Restate the main motion before taking a vote.

G. Lead the Board to develop clear instructions on review issues for correspondence to the researcher.

H. Use general consent when possible (e.g., "If there are no objections…").

I. Allow the withdrawal of motions using general consent.

4.3.3 Types of Motions

A. Main motions:

- Cannot interrupt a member who has been assigned the floor.
- Require a second, unless the motion is from a committee.
- Can be debated.
- Can be amended.
- Require a majority vote.

B. Secondary motions:

- Can be made while the main motion is on the floor and before it has been decided.
- Three classes: subsidiary motions; privileged motions; incidental motions.

C. Subsidiary Motions:

- Subsidiary motions relate directly to the main motion on the floor.
- They have rank among each other: a motion of higher rank can be made at the time when a motion of lower rank is on the floor or pending; the motion of higher rank takes precedence:
    1. Previous Question (call for the vote) – Highest Rank
    2. Limit or Extend Limits of Debate
    3. Amend
    4. Main Motion – Lowest Rank

Amend: Changes the wording of a motion to make it clearer, more complete or more acceptable *before* the motion is voted upon.

- An amendment must be germane to the motion on the floor.
- A member must obtain the floor to offer an amendment.
- An amendment must be seconded.
- An amendment is debatable if it is made to a debatable motion.
- A primary amendment can be amended; the secondary amendment cannot.
- An amendment requires a majority vote even when applied to a motion that requires a two-thirds vote.
- Adopting an amendment does not adopt the motion.
- Amendments that are the same as a negative vote on the motion are out of order.

Limit Debate: Exercises special control over the debate by reducing the number and length of speeches allowed or by requiring that debate be limited to a period of time after which the vote must be taken.

- Can be used with any motion.
- Must be seconded.
- Is not debatable.
- Can be amended but only regarding the number and/or length of speeches or when the vote will be taken.
- Requires a two-thirds vote.

Previous Question:

- Can be applied to any pending question.
- It is out of order when a member has the floor.
- It cannot be debated.
- Requires a two-thirds vote.

D. Privileged Motions:

- Privileged motions are not related to the business on the floor but to the rights of members and the organization.
- The Chair can move for recess or adjournment by using general consent.

Recess: Proposes a short intermission in the meeting.

- It must be seconded.
- It cannot be debated.
- It can be amended only as to the length of time or recess.
- It requires a majority vote.

Adjourn: Closes the meeting.

- It must be seconded.
- It cannot be debated.
- It cannot be amended.
- It requires a majority vote.

E. Incidental Motions:

- Have no rank among themselves and may be applied to any main motion; usually decided as they arise, they are usually not debatable and can only rarely be amended.

Point of Order: To raise the possibility that rules of order are not being followed.

Point of Information: To obtain additional information on the subject being considered.

Division of Question: Used when a motion contains several parts, and the group wishes to vote on each part separately:

- It requires a second.
- It requires a majority vote.

F. Restorative Motions:

- Allows the group to change its mind on previously adopted motions.

Rescind: Used to quash or nullify a previously adopted motion:

- It requires a second.
- It requires a two-thirds vote.
- It is not in order if action has already been taken as a result of adoption of the motion.

Reconsider: Used to reconsider the vote on a previously adopted motion:

- Can only be made by someone who voted on the prevailing side.
- Must be made on the same day that the vote to be reconsidered was taken.
- It requires a second.
- It may be debated, and it opens up to debate the motion to which it is applied.
- It requires only a majority vote.

4.3.4 Process

A. The floor is assigned to the primary reviewer.

B. The primary reviewer presents the proposal and the issues, and makes a motion for disposition of the proposal.

C. A motion is seconded.

D. The Chair states the motion (the motion is pending).

E. Debate is held "one speaker at a time."

F. The Chair may open the floor to general discussion.

G. The Chair puts the question to vote.

H. Votes are taken by a show of hands.

I. The Chair announces the vote.

J. If the motion fails to pass, the floor is open to alternative motions from any member of the Review Board.

4.3.5 Other Points

A. The maker of a motion has the first right to speak about it.

B. A member can vote against his/her own motion, but cannot speak against it.

C. A member can modify his/her own motion *before* it is stated by the Chair.

D. A member can amend his/her own motion *after* it has been stated by the Chair.

E. A member can withdraw his/her own motion up to the time it is stated by the Chair, and after that with the group's permission (e.g., with general consent).

F. Motions that repeat the same question on the same day, or that conflict with an already adopted motion, are out of order.

4.3.6 Voting and Disposition Decisions

A. All votes on motions for disposition are taken by a show of hands; the number in favor, opposed, and abstaining are recorded.

B. To be adopted, a majority of members present at the meeting must vote in favor.

C. In a full-Board review, the Chair may vote only to break a tie vote.

D. For proposals being reviewed under expedited review authority, or by subcommittee, the majority also prevails.

E. Disposition Decisions:

- **Approve:** The proposal can be approved as submitted or amended prior to the Review Board meeting.

- **Conditionally Approve:** Simple concurrence of the researcher to a specified set of conditions is all that is required for approval of the proposal. Final approval is delegated to a subcommittee; there is no need for review at another Review Board meeting.

- **Defer Consideration:** The number of issues, concerns and/or questions is too great to be resolved by the simple concurrence of the researcher. The issues must be

addressed in a revised proposal which is considered in a subsequent Review Board meeting.

- **Disapprove:** This is moved only after the investigator has been given an opportunity to resolve serious issues, and further attempts to negotiate required revisions would be unproductive. While this disposition effectively terminates the proposal, the investigator is free to submit a new proposal for consideration at a later Board meeting.

- **Suspend Approval:** This action is taken by the ES/AES when investigators fail to submit information required for continuation review and approval prior to expiration of study approval. This action is also taken by the ES/AES in concurrence with the Chairperson when adverse events or unanticipated problems involving risks to subjects or others requires temporary suspension of study activities, except to the extent that suspension would pose additional risks to subjects.

- **Terminate Approval:** This action is taken by ES/AES with the concurrence of the Chairperson in instances in which the investigator fails to submit information required for continuation review and approval within 30 days of expiration of study approval. This action is taken by the full Board when serious and continuing non-compliance with federal, state, institutional or WSIRB requirements have occurred which the investigator has failed to resolve to the satisfaction of the Review Board.

4.3.7 Appeals of WSIRB Decisions

Investigators have the right to appeal negative Review Board decisions, including disapprovals, terminations of approval, restrictions on study design and/or study procedures, and approval conditions. Appeals must be submitted in writing to the Review Board within 60 days of the written notice to the investigator of the Review Board decision. To be successful, appeals should provide a rationale for why the Review Board's decision is in error, is not consistent with the *Washington State Agency Policy on Protection of Human Research Subjects* and/or the *WSIRB Procedures Manual*, or is not inconsistent with these policies and procedures but is unreasonable given the circumstances and constraints of the proposed research.

All written appeals, including those of decisions made through the expedited review process, will be placed on the agenda of the next meeting of the Review Board. Investigators may request to be present at the meeting during consideration of the appeal to answer questions from

Review Board members and/or to clarify aspects of the proposed research they believe the Review Board has not adequately taken into consideration. The investigator must leave the meeting prior to final consideration of the appeal.

A motion for disposition of the appeal, and the rationale for that disposition, is made by the primary reviewer of the proposal. After the motion is seconded, the Chair opens the floor to debate on the motion. After debate, the Chair puts the question to vote. Votes are taken by a show of hands and a simple majority is needed for the motion to pass.

If unsatisfied with the Board's decision on the appeal, the investigator may, within 30 days of the appeal decision, request in writing that the appeal be re-considered by an ad hoc WSIRB Appeals Committee. The WSIRB Appeals Committee shall be comprised of three randomly selected members from Review Board A and three randomly selected members from Review Board B, to exclude the ES/AES. The Chairperson of the Review Board in which the original decision was made shall chair the WSIRB Appeals Committee, and shall have a vote on the final decision. The ES/AES will form the WSIRB Appeals Committee and schedule the meeting, which may be conducted by teleconference, if necessary, to ensure timely consideration of the appeal. Decisions made by the WSIRB Appeals Committee are final and are not subject to further review or appeal.

4.4 Confidentiality of Review Board Materials

All materials listed below are considered confidential and shall not be disclosed to or discussed with any individual who is not a member of the Review Board on which the proposal is being considered. The only exception to this rule is that the Chairperson, the primary reviewer of the proposal, and the ES/AES may discuss the proposal with the principal investigator and his/her staff prior to the meeting; and the ES/AES may discuss the disposition of the proposals with the principal investigator and his/her staff after the meeting.

4.4.1 Confidential Materials

The following materials are considered confidential:

- Proposals submitted to the Review Board, unless and until they have been approved by the Board. Disapproved proposals and proposals canceled before approval shall remain confidential.

- Oral and written arguments, opinions, and decisions (votes) by individual Board members during the review process. Meeting minutes summarize discussion and votes in anonymous form, except for abstentions.

- Written reviews of proposals by outside consultants.

- Correspondence between the Review Board and the investigator prior to approval of the proposal. Correspondence with investigators of disapproved proposals shall remain confidential.

- Any identifiable personal records and/or information pertaining to agency clients, employees, or members of the general public made available to the Review Board in the process of review.

Board members should keep confidential review documents and correspondence in a secure location at all times. Confidential review documents and correspondence transmitted as email attachments to Board members are accompanied with a statement that the materials are confidential and should be opened only by the intended recipient. Upon completion of Board membership, Board members must surrender accumulated confidential materials to the Review Section or destroy these materials by discreet recycling[2], or in the case of identifiable personal records, by shredding or burning.

4.4.2 Retention of Confidential Materials

To minimize storage of paperwork related to Review Board business, members may destroy all review materials (except identifiable personal records) by discreet recycling when the meeting is completed, except for the following:

- Complete copies of all Review Board minutes, which should be retained indefinitely.

- Copies of all proposals, correspondence, and responses from investigators for proposals for which a member is the primary reviewer, including those reviewed under expedited procedures. All materials for which a member is the primary reviewer should be retained until the project is completed or canceled.

- Copies of proposals that will be discussed in a future meeting (i.e., any proposal deferred or carried over to a future meeting because of unresolved issues), until final disposition has been determined. If a proposal has been revised, earlier copies may be discreetly recycled when the revised proposal is received.

All other Board-related paperwork (correspondence, agendas, cover memos, proposals, progress reports, etc.) may be discreetly recycled after the meeting to which they pertain has been completed.

[2] Discreet recycling of materials is achieved by distributing materials in one or more recycle barrels in a manner that mitigates against identifiable information being recognized by a casual observer.

4.5 Record Keeping

4.5.1 Research Project Files

The Review Section maintains separate project files for each research proposal. Upon submission, proposals are assigned a project code. The project code appears as "X-mmddyy-X" and consists of a single letter prefix assigning the project to either Board A or B, followed by the date the application is received by the Review Section, and ending with a single letter suffix indicating the agency in whose jurisdiction the research would be conducted ("S" for DSHS; "H" for DOH; "L" for L&I; or "U" for unaffiliated or other). Research that is in a Washington State Agency jurisdiction but which is reviewed by another IRB under an IRB Authorization Agreement is assigned a prefix of "C" to designate it is a cooperative review.

Each project file contains, in order from front to back:

- A *Face Sheet* created by the Lotus Notes database.
- A copy of the *Project Application Summary* (Form A).
- Documentation of Training in the Protection of Human Subjects completed by the principal investigator, unless such documentation is included in the Review Section's Training Database.
- A *Documentation of Findings* based on the WSIRB review of the proposal.
- An approved proposal, with addendums as applicable, which reflects Board-negotiated revisions in the original proposal, and which officially represents how the research will be conducted.
- The original signed and executed Confidentiality Agreement, if identifiable personal records maintained by these Washington State Agencies are used or disclosed in the research.
- All other correspondence and documentation related to the project, in reverse chronological order.
- The Summary of Pre-Review Issues completed prior to full-Board review of the proposal originally submitted.

The Review Section also maintains electronic files with electronic copies of all proposals submitted for review, including mark-up copies of proposals revised at the request of the Review Board. Hard copies of earlier and/or outdated versions of proposals are discarded from the

paper file and replaced with a placeholder which identified the location of the document in the electronic file maintained on the Review Section's hard drive.

4.5.2 Record Storage and Retention

Proposals reviewed by the Board and all materials and documents related to the Board review are maintained in individual project files stored in locked file cabinets in the DSHS Human Research Review Section. Only staff in the Review Section have direct access to materials in the locked file cabinets.

Project files are retained in the Review Section for at least 12 months after the project is completed or canceled. The files are then moved to the Washington State Records Center where they are retained for seven years. Within these retention parameters, all project files are accessible for inspection and copying by authorized representatives of the U.S. Department of Health and Human Services at reasonable times and in a reasonable manner.

Materials which have historical value may be selected and retained in the Washington State Archives indefinitely.

4.5.3 Review Board Correspondence

Review Board correspondence is prepared by the ES/AES assigned to the proposal and who has attended the meeting in which the proposal was considered. Correspondence is written to represent the consensus view of the Review Board; however if a strong minority viewpoint is expressed in the meeting it will be included in the correspondence. Draft correspondence must be reviewed for accuracy and tone by the primary reviewer before it is mailed to the investigator. Other Review Board members may request that they also review and comment on draft correspondence. Review Board correspondence is signed by the ES/AES on behalf of the Review Board.

Review Board correspondence in response to expedited reviews is prepared by the ES/AES who participated in the review of the proposal. The primary reviewer may request to review and comment on draft correspondence prepared by the ES/AES; however, under normal circumstances this review is not necessary.

Correspondence is sent by first class mail to investigators. If the response is time-sensitive, an electronic copy of the letter is attached to an email sent to the investigator. Copies of all written correspondence and emails are included in the project file maintained in the Review Section.

4.5.4 Review Board Meeting Minutes

Meeting minutes are drafted by the Associate Executive Secretary after all Review Board disposition letters have been conveyed to investigators. The review of a proposal is described in the minutes based on Board correspondence to investigators. The meeting minutes include:

- The time the meeting was called to order.
- Attendance and quorum verification.
- Documentation of the acceptance of the minutes of the previous Board meeting.
- The Executive Secretary's report.
- Documentation of whether any member in attendance has a personal or financial conflict of interest with respect to any item on the meeting agenda.
- A brief description of the proposal, progress report for continuation review, study amendment, or report of adverse event and/or unanticipated problem submitted for full-Board review, along with a description of the Review Board's deliberations, actions, and votes on each item. The minutes document the basis for requiring changes or for disapproving research and include a summary of controverted issues, if applicable.
- A list of new proposals, study amendments and progress reports reviewed under expedited review authority, and any Board member comments and questions.
- Other Review Board actions.
- The time the meeting was adjourned.

4.5.5 Review Board Member List

The HRRS maintains a current Review Board membership list, including names; earned degrees; relevant experience such as board certifications, licenses, etc., sufficient to describe each member's principal anticipated contributions to Review Board deliberations; and any employment or other relationship between each member and the institution. Changes to Board membership are reported promptly to the federal Office of Human Research Protections.

4.5.6 Written Procedures

HRRS staff maintain current written procedures for the WSIRB. Written procedures are codified in the *WSIRB Procedures Manual*, which is available on the WSIRB website: http://www1.dshs.wa.gov/rda/hrrs/ and included in the WSIRB Board Member Handbook. Proposed revisions and/or additions to procedures are prepared by HRRS staff and distributed in mark-up format to the Review Board. Review and comments on revisions and/or additions to procedures are solicited from Board members prior to adoption. Formal adoption of the *WSIRB Procedures Manual* is by vote at a convened Review Board meeting. The date of the current version of the *WSIRB Procedures Manual* is listed in the footer on each page.

4.5.7 Research Tracking System

The Review Section maintains a Lotus Notes Tracking Database to manage and track active as well as completed research protocols. The Tracking Database serves as a historical record of all proposals reviewed by the Board. It is also used to produce a list of projects due for continuation review before each review cycle; to generate routine Review Board correspondence; to evaluate Review Board and the Review Section workload; and to prepare the *Activity Report* published every fiscal year by the Review Section.

4.6 Methods of Documentation

4.6.1 Education and Training

Principal investigators must document completion of training in protection of human research subjects before their proposals can be approved. The Review Section will accept certificates of completion of such training from recognized institutions. The University of Washington and Fred Hutchinson Cancer Research Center list on their websites investigators who have completed their training. Investigators who complete the CITI training offered through these Washington State Agencies are included on reports sent to the Review Section by the University of Miami, the CITI host institution.

The Review Section maintains a Training Database of all persons who have completed the requirements for education and training in the protection of human research subjects who are involved in research under Washington State Agency jurisdiction. The Training Coordinator is responsible for updating and maintaining the Training Database from the sources listed above. The Training Coordinator works with the DSHS webmaster to ensure that a current list of training participants is posted on the Review Section website.

4.6.2 Informal Review and Consultation

The ES/AES provide consultation to researchers, students, program managers, and Washington State Agency employees on a wide variety of topics related to the human subjects protection program. Many consultations involve inquiries about whether a specific activity constitutes research under the *Washington State Agency Policy on Protection of Human Research Subjects* (See Section 5.1, *WSIRB Procedures Manual*, Determining if an Activity Requires WSIRB Review and Approval).

A decision about whether an activity constitutes research must be based on an informal review of a written document that describes the activity, including the intent of the activity, in sufficient detail to allow the determination to be made. The determination is made in writing and either mailed or emailed to the originator of the inquiry. The informal review and determination are documented in a file created by the ES/AES. At a minimum, the file includes the name and affiliation of the person making the inquiry, a written description of the activity in question, a written determination about whether the activity constitutes research, and the date the determination was made. Individual files are maintained in a central file cabinet in the Review Section.

4.6.3 Exemptions from Review

Proposals that are found exempt under the *Washington State Agency Policy on Protection of Human Research Subjects* are entered into the Tracking Database as exempt. These proposals are not subject to annual review. However, the investigator is notified at the time of initial review that if the activity is amended in a manner such that it is no longer exempt, he/she must inform the Review Board by submitting a *Request for Study Amendment* form. If information on the form indicates the study is no longer exempt, the amended proposal will be reviewed either through the expedited or full-Board procedure, and the status in the Tracking Database will be changed to reflect the review.

4.6.4 Findings Required by Regulation

Upon conditional approval or approval of a project reviewed by either expedited or full-Board procedures, the ES/AES will complete a *Documentation of Findings* form. This form includes information abstracted from the proposal submitted by the investigator as well as the results of the review of the proposal. The form meets requirements in 45 CFR 46 and 45 CFR 164.512(i) for documenting the findings and actions of the Review Board, including:

- Project title, principal investigator, and primary reviewer.
- Type of review conducted and approval date.
- Justification for expedited review, if applicable.
- Period of Review Board approval.
- Level of risk to subjects.
- Additional protections for pregnant women and human fetuses involved in research, if applicable. (45 CFR 46, Subpart B)
- Additional protections for prisoners involved in research, if applicable. (45 CFR 46, Subpart C)
- Additional protections for children involved in research, if applicable. (45 CFR 46, Subpart D)
- Waiver of some/all elements of consent for study participation, if applicable. (45 CFR 46.116(d))
- Waiver of written documentation of consent; oral consent will be obtained, if applicable. (45 CFR 46.117(c))
- Waiver of parental permission for study participation of a child, if applicable. (45 CFR 46.408(c))
- Waiver of authorization for disclosure of individually identifiable private information and/or protected health information, if applicable. (45 CFR 46.116(d)); 45 CFR 164.512(i); RCW 70.02.050(g); RCW 42.48.020)

The completed *Documentation of Findings* form is signed by the ES/AES, a copy is mailed to the investigator with the WSIRB approval letter, and the original is filed in the project file.

4.6.5 Review by Another IRB

In the course of review, the Review Board may request documentation of study approval by the funding agency's IRB, from the IRB of the investigator's home institution, or from other IRBs which retain jurisdiction over the research. Such documentation is included in the project file maintained in the Review Section.

5.0 REVIEW PROCESS

5.1 Determining if an Activity Requires WSIRB Review and Approval

Activities that include many of the features of research may not necessarily require review and approval by the WSIRB. Some activities resemble research but actually are not research as defined in the federal regulations. Other activities meet the definition of research but are exempt from needing WSIRB review and approval.

5.1.1 Research versus Non-Research Activities[3]

Research is defined in the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." There are a variety of activities that employ many of the features of research, such as rigorous design, systematic data collection and statistical analyses, which are nevertheless not considered research under this definition. The key to distinguishing between research and non-research activities is to determine the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of similar activities that are not research may be to prevent or control disease in a population or to identify methods of improving services to a group of clients or customers.

Some activities conducted by or on behalf of institutions which involve systematically collecting and analyzing data are not research. Included in this category are audit activities, resource and/or drug utilization studies using institutional records, and client outcome monitoring in which individual level data are routinely collected and analyzed to determine the extent to which clients are experiencing the intended outcomes of a program. Client satisfaction and needs assessment surveys which only collect information from clients who are eligible to receive program services are also included in this category. If the primary intent of these activities is to support the administration of the program, and if data collection is limited to information needed to administer the program, these activities are not considered research. The HIPAA Privacy Rule classifies such activities as part of "health care operations" and not research. However, data collected through such activities could be used secondarily for research, in which case WSIRB review and approval is required.

Program evaluation, surveillance activities, disease investigation and/or emergency response activities, and quality assurance and/or quality improvement are activities that may or may not constitute research that

[3] This section draws heavily on the "Guidelines for Defining Public Health Research and Public Health Non-Research," published by the Centers for Disease Control and Prevention, October, 1999.

requires IRB review. The WSIRB uses the following guidelines to determine when activities in these categories constitute research that requires IRB review and approval:

Program evaluation activities in which the primary intent is to assess the success of an established program or intervention in achieving its objectives in a specific population, and in which the information gained will be used only to provide feedback to the program, to ensure service quality, or to make improvements in the program, are not considered research. However, when the primary intent is to test a new, modified, or previously untested intervention, service, or program in a defined population to determine whether it is effective, the evaluation is research. The systematic comparison of standard or non-standard interventions in an experimental-type design also is research.

Surveillance activities which involve the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in a population and which are authorized by state statute or regulation which specify the intent of the activity, its purpose, and uses of the data, are not considered research. Quality control activities that assess, for example, completeness of reporting of surveillance data by matching case records with records from other databases are not considered research. However, when health-related data are collected in surveillance systems and analyzed with the primary intent to produce knowledge applicable to other populations and settings from which the data were collected, or to contribute to new knowledge about the health condition, the activities are likely to be research. Surveillance systems that involve longitudinal data collection systems (e.g., follow-up surveys and registries) that allow hypotheses testing, which collect more information than the occurrence of a health-related problem, in which etiologic analyses can be conducted, or in which cases may be identified to be included in subsequent studies, are likely to be research.

Disease investigation and/or emergency response activities authorized under state statute or regulation which are undertaken to identify, characterize, and solve an immediate health problem, and in which the information gained will directly benefit those participants involved in the investigation or their communities, are not considered research. However, when biological samples are stored for future use intended to produce generalizable knowledge, or when additional analyses are conducted beyond those needed to solve the immediate health problem, the activity may have a research component. When investigational new drugs or devices are used, or when drugs are used off-label, the activity is almost always considered research. Whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

Quality assurance and/or quality improvement activities[4] in which existing individual level data are collected and analyzed and in which there is a formal commitment in advance of data collection to a corrective action plan related to any of a number of possible outcomes of the analysis are not considered research. However, prospective interventional activities which may involve systematic comparison of standard or non-standard therapies are considered research even when conducted by the entity responsible for quality assurance and/or quality improvement.

Activities conducted for educational purposes may fall into a category that would not be considered research if the activity was not conducted primarily for educational purposes. For example, the design of a thesis or dissertation project might be classified as program evaluation or a quality improvement activity rather than research if it was being conducted primarily to support the administration of a program or to develop a corrective action plan. However, as the primary intent of the activity is related to training in research methods in partial fulfillment of requirements for an advanced degree, the educational activity is considered research.

Investigators should consult with staff in the Human Research Review Section (HRRS) if they have questions about whether a specific activity is considered research. The HRRS Manager is responsible for making the determination of whether or not an activity is considered research. If the investigator disagrees with the determination made by the HRRS Manager, the Human Protection Administrator of the state agency that has jurisdiction over the activity in question shall make the final determination.

5.1.2 Research Exempt from Review

Once an activity is determined to be research, a determination should be made as to whether the activity involves human subjects as defined in the federal regulation. Human subject means "a living individual *about whom* an investigator conducting research obtains (1) data through intervention or interaction with the individual, of (2) identifiable private information."

If the activity is determined to be research that involves human subjects, a determination should be made about whether the research falls into a category of research that is exempt from needing review and approval by the WSIRB. To qualify for exemption from WSIRB review, a research proposal must fall into one of the categories that are listed in Section XI of the *Washington State Agency Policy on Protection of Human Research Subjects*. These categories are more restrictive than the federally approved exemption categories, and reflect a higher local standard for what can be excluded from WSIRB review.

[4] Based on "The Quality Improvement-Research Divide and the Need for External Oversight," Eran Bellin and Nancy N. Dubler, American Journal of Public Health, Sept 2001, Vol 91, Issue 9, p1512

5.1.3 Procedures for Determining if an Activity Requires WSIRB Review and Approval

Washington State Agencies staff and outside investigators are expected to contact the ES/AES to inquire about whether a planned activity constitutes research which requires review and approval by the WSIRB. Contact should be made at least 60 days prior to any planned contact with potential subjects or access to individually identifiable personal records. After discussion with the ES/AES, the agency employee or outside investigator will be advised whether to submit an *Exempt Review Form* to the HRRS. The *Exempt Review Form* and supporting information and documents about the planned activity may be submitted electronically to wsirb@dshs.wa.gov. Washington State Agency staff and outside investigators will be informed in writing within five days about whether the planned activity requires submission of an application for review and approval by the WSIRB.

5.2 Research Application Submission Procedures

Investigators planning to submit a proposal to the Washington State Institutional Review Board should contact the HRRS to discuss their proposed research before completing and submitting their proposals for review. Investigators are required to notify the HRRS of their intent prior to submitting a proposal. Investigators not affiliated with the Department of Social and Health Services, Department of Health, or Department of Labor and Industries, must sign an *Unaffiliated Investigator Agreement* and submit it with their application to the WSIRB. Investigators whose agency of affiliation (e.g., university) maintains a registered institutional review board (IRB) must submit their proposals to their institution's IRB office prior to submitting the proposal to the Washington State Institutional Review Board. However, in most cases the investigator is not required to obtain final IRB approval from his or her home institution prior to submitting the proposal to the WSIRB.

5.2.1 Research Application Forms

Research proposals must be submitted to the Review Board on the official WSIRB application forms available on the Review Section's website: http://www1.dshs.wa.gov/rda/hrrs/. Investigators may cut and paste relevant information from project narratives developed for applications to a federal, public, or private funding source into the WSIRB application forms. However, investigators must follow the instructions in the application forms and provide all the required information in their application. In general, the background section and literature review should be no more than several pages in length. However, proposals must be complete, and must include a written protocol, any proposed informed consent documents, any proposed data collection instruments, the investigator's brochure (if one exists), and any recruitment materials, including advertisements intended to be seen or

heard by potential participants. If the research is supported by a federal grant or contract, one copy of the original grant application should be included in the submission.

5.2.2 Submission Timelines

- Full Board Review: Research applications requiring full Board review must be submitted electronically to wsirb@dshs.wa.gov by the published deadline date for each scheduled Board meeting, which is posted on the HRRS website. The ES/AES will notify investigators within one week of any revisions needed in the application. Investigators will have one additional week to make necessary revisions and to submit a revised application with original signatures and twenty paper copies to the HRRS for distribution to the full Review Board.

- Expedited Review: Research applications that qualify for expedited review may be submitted to HRRS at any time. Research applications eligible for expedited review must be submitted electronically to wsirb@dshs.wa.gov. The ES/AES will notify investigators within one to two weeks of any revisions needed in the application. Investigators will be asked at that time to submit a revised application with original signatures and four paper copies to the HRRS.

5.2.3 Non-Scheduled Review

Under special circumstances, and at the discretion of the ES/AES, non-scheduled reviews of proposals that do not qualify for expedited review may be conducted by videoconference. Reviews conducted by videoconference are subject to the same quorum requirements that apply to regularly scheduled meetings of the Review Board.

Non-scheduled reviews are limited to the following:

- Initial review of a proposal, or review of an investigator's response to the Board's review issues when consideration of the proposal has been deferred at a scheduled meeting, when delay until the next regularly scheduled Board meeting would make the conduct of the proposed research impossible or would unacceptably affect the soundness and integrity of the ongoing research;

- Review Board consideration of any unexpected adverse events or unanticipated problems involving risks to subjects or others, or serious and continuing noncompliance with Board-approved procedures.

Investigators who believe their circumstances justify WSIRB consideration through a non-scheduled review process may contact the ES/AES to request a non-scheduled review.

5.2.4 Cooperative Review

The Washington State Institutional Review Board has Cooperative IRB Review Agreements with the University of Washington IRB and the Fred Hutchinson Cancer Research Center IRB. These agreements are intended to reduce the number of proposals that require review by both IRBs when the research is in the joint jurisdiction of both institutions. Copies of these Cooperative Agreements are posted on the Review Section's website: http://www1.dshs.wa.gov/rda/hrrs/HRPubl.htm.

5.2.5 Reliance on the Review of Another IRB

Procedures are available for the home institution of an investigator who is submitting an application to the WSIRB to rely on the WSIRB review rather than to conduct their own IRB review of the research. These procedures are intended to minimize redundant reviews and to conserve time and resources for both the investigator and IRB members and staff. Establishing an *IRB Authorization Agreement* documents an arrangement in which one institution relies on the review of an IRB at another institution for a single research proposal or group of research proposals. This Agreement must be signed by the signatory official of each institution and kept on file at the IRB offices of the respective institutions.

In some instances, these Washington State Agencies will rely on the review of an IRB at another institution. An example would be a situation in which IRB review is required for the use of a non-approved device or drug in a surveillance activity or an emergency disease investigation. If a central IRB has authority to conduct such a review on behalf of local study sites, these Washington State Agencies may elect to rely on that review to expedite early implementation of the protocol in the field. Another example would be the interview of one subject in an ongoing research project who has been placed in a DSHS institution subsequent to enrollment in the study. Washington State Agency administrators and/or investigators who believe a research activity meets these circumstances should discuss this option with the HRRS Manager, who will make the initial determination about whether to rely on the review of another IRB. Final decisions about relying on the review of an IRB at another institution will be made by the Human Protection Administrator of the state agency that has jurisdiction over the activity in question.

If a decision is made to rely on the review of another IRB, the investigator must initiate establishment of an IRB Authorization Agreement between his/her home institution and the Washington State Agency in whose jurisdiction the research would be conducted. The research may not

commence in the Washington State Agency until the IRB Authorization Agreement has been signed by the respective Institutional Officials. The application submitted to the reviewing IRB must be submitted to the HRRS, along with documentation of IRB approval and of any restrictions or conditions on the research imposed by the reviewing IRB. The HRRS will open a project file for the research reviewed by another IRB. Progress reports submitted for continuation review and documentation of continuation approval will be requested from the reviewing IRB by the HRRS.

5.2.6 "Just-In-Time" Review Procedures

Applications for federal funding for research may qualify for "just-in-time" review procedures. Under these procedures certification of IRB approval is not required at the time of application, but may be deferred until just prior to an award being made but at least 60 days prior to contacts with potential human subjects. Investigators should inquire with their federal project officer to verify that "just-in-time" procedures will apply to their application. If so, investigators should submit their proposal for WSIRB review when they are informed that the application for federal funding has received a score in the fundable range, or when they learn that the proposal may be funded.

5.2.7 Human Subjects Protection Training Requirements

The Washington State Agency training requirements are grounded in federal recommendations and reflect a belief that appropriate education and training is an important component of an effective system of human subjects protection.

All principal investigators submitting new research proposals to the WSIRB must have completed training in human subjects protection before their research will be approved. All research staff responsible for the design of the study and all those in contact with human subjects and/or identifiable data (e.g., interviewers, and data analysts) are strongly encouraged to complete the training. Principal investigators of ongoing research projects must complete training before continuation approval for their research will be extended. Retraining is required every three years.

Investigators may satisfy this education and training requirement through one of several ways:

- By completing a course in the protection of human research subjects at their home institution and submitting to the HRRS written documentation of the content of the training and the date it was completed.

- By attending an in-person tutorial session offered quarterly through the University of Washington and the Fred Hutchinson Cancer Research Center. Class schedules, locations and registration information are available at the University of Washington: http://dept.washington.edu/hsd/INFO/train.htm.

- By completing the web-based training in the Protection of Human Research Subjects provided by CITI/University of Miami. There is no charge to investigators if they access this training through the HRRS website: http://www1.dshs.wa.gov/rda/hrrs/hrtraining.htm. Members must complete all 14 modules and the quizzes for these modules and review the *Washington State Government Agencies Institutional Page* and links to receive credit for training. For those who have completed the main course, a Continuing Education Course in the Protection of Human Subjects is also available at the CITI/University of Miami site.

The HRRS maintains a training participant database to track completion of training, and provides a current training participant list on the HRRS website: http://www1.dshs.wa.gov/rda/hrrs/list/hrtraipartic.htm.

5.2.8 Applications that Request Disclosure of Confidential Records

Use and/or disclosure of individually identifiable personal records and/or protected health information for research purposes requires the written consent or authorization of the person to whom the information pertains. In some situations, however, it may be impossible to obtain written consent or authorization for the research use or disclosure. In this case, the investigator may ask the WSIRB to approve a waiver of the consent or authorization requirement. The WSIRB can approve such a waiver only if requirements in applicable statutes and regulations are satisfied.

The state laws and federal regulations which define the requirements that must be met for the WSIRB to approve a waiver of consent or authorization depend on the information that is being requested. The most common applicable laws and regulations that must be satisfied are:

- All requests for research use and/or disclosure of identifiable personal record information and/or protected health information must satisfy the requirements in 45 CFR 46.116(d).

- All requests for research use and/or disclosure of protected health information must satisfy the requirements in 45 CFR 164.512(i)

- All requests for research disclosure of identifiable personal record information (including protected health information) from DSHS and DOH must satisfy the requirements in RCW 42.48.020.

- All requests for research use and/or disclosure of health care information from a health care provider must satisfy the requirements in RCW 70.02.050(g).

The unduplicated criteria that must be satisfied in two laws and two regulations are listed in Form H2 of the *WSIRB Research Application Forms*. If one or more of these two laws and two regulations do not apply to a specific data request, the investigator is not required to address the specific criteria that pertain to that particular law or regulation.

Depending on the information being sought, other laws and regulations must be satisfied for the WSIRB to approve a waiver of consent or authorization for use and/or disclosure of the information. A partial list of record information and the applicable law or regulation that pertains to its use and/or disclosure follows:

- *Aging and disability client services information* is subject to requirements in RCW 74.04.060

- *Arrest records* held by the Washington State Patrol are subject to requirements in RCW 10.97.050.

- *Child abuse and/or child welfare* record information is subject to requirements in 45 CFR 1340 §14.

- *Child support enforcement* records are subject to requirements in RCW 74.20.280 and RCW 26.23.120.

- *Criminal history information for juveniles* is subject to requirements in RCW 13.50.010 and RCW 13.50.050.

- *Criminal history information for adults* is subject to requirements in RCW 10.97.050.

- *Department of Health registries* are subject to requirements in the following statutes and regulations:

  Cancer -- WAC 246-102-070
  CHARS -- WAC 246-455-080
  HIV/AIDS/STD -- RCW 70.24.105 and WAC 246-101-635
  Lead -- WAC 246-101-610 and RCW 42.48
  Newborn screening – RCW 70.83.020, WAC 246-650-030
  Trauma -- RCW 70.168.090 and WAC 246-976-420
  Vital records -- RCW 70.58.104, RCW 70.58.082 and WAC 246-490-030

- *Driver's license information* held by the Department of Licensing is subject to requirements in WAC 308-10-050 and 18 USC 2721(b)(5).

- *Education/school records* are subject to requirements in Title 20, USC, Chapter 1232h, Protection of Pupil Rights, 34 CFR Part 98, Student Rights in Research, Experimental Programs, and Testing, and 34 CFR Part 99, Subpart D.

- *Food stamp information* is subject to requirements in RCW 74.04.060

- *Medicaid record information* is subject to requirements in 42 CFR 431.300.307 and RCW 74.04.060

- *Mental health treatment information* is subject to requirements in RCW 71.05.390, RCW 71.05.630, RCW 71.05.620 and RCW 71.34.200

- *Minor's record information* for various programs is subject to requirements in the following statutes:

  STD testing/treatment -- RCW 70.24.110.
  Mental health -- RCW 71.34.030, RCW 71.34.200, and RCW 71.34.042.
  Substance abuse treatment -- RCW 70.96A.095, RCW 70.96A.235, and RCW 70.96A.250.

- *Nursing home patient assessment information* in the Minimum Data Set is subject to requirements in 42 CFR 483.315

- *Public assistance record information* is subject to requirements in RCW 74.04.060.

- *Substance abuse treatment information* is subject to requirements in 42 CFR Part 2 §52, RCW 70.96A.095, RCW 70.96A.150, and RCW 70.96A.235.

- *Unemployment insurance records* held by the Department of Employment Security are subject to requirements in RCW 50.13.015 and RCW 50.13.020.

- *Vital records* are subject to requirements in RCW 70.58.104

- *Vocational rehabilitation records* are subject to requirements in 34 CFR Part 361 §38 and WAC 490-500-555

- *Wage and income records* held by the Department of Employment Security are subject to requirements in RCW 50.13.060

- *Worker's Compensation records* held by the Department of Labor and Industries are subject to requirements in RCW 51.36.060

Form H2 in the *Research Application Forms* require investigators to provide information needed by the WSIRB to determine whether requirements in the first two laws and two regulations can be satisfied. Investigators requesting information subject to other requirements in law or regulation are advised to provide information to allow the IRB to determine that those requirements have been met. Use the links above to find out what these requirements are.

Per RCW 42.48.020(c), disclosure of identifiable personal record information held by DSHS and/or DOH for research purposes is subject to the establishment of a legally-binding confidentiality agreement. This agreement is prepared by WSIRB staff and sent to the investigator for signature with the WSIRB letter approving the research proposal. After signing the agreement, the investigator must return it to the ES/AES, who will forward it for signature by the DSHS and/or DOH administrator authorized to disclose the information for research purposes. When signed by the agency administrator the agreement authorizes disclosure of the confidential record information needed for the research. A copy of the signed agreement is sent to the investigator and to the program manager responsible for disclosing the data to the investigator. The agreement remains in effect until all terms of the agreement, including permanent destruction of the ability to identify the records disclosed, have been satisfied.

Identifiable personal record information may be used only for purposes that are described in the confidentiality agreement. Investigators are not authorized to redisclose or provide access to the record information to other individuals without the prior written approval of the WSIRB. Investigators are not allowed to attempt to deidentify identifiable personal record information for the purpose of redisclosing or providing access to the record information without the prior written approval of the WSIRB.

Use of record information for thesis, dissertation or other educational purposes not described in the original proposal approved by the WSIRB must be submitted for review and must receive prior approval before student use of the personal records will be authorized. Any such unauthorized use or disclosure of personal records is a violation of terms of the confidentiality agreement. The principal investigator will be held accountable under RCW 42.48.050 for each violation.

5.3 Review and Approval Considerations

The Review Board is guided by federal regulations, the Belmont Report, institutional policies, and applicable state laws and regulations. The *Washington State Agency Policy on Protection of Human Research Subjects* is based on the federal regulation for the protection of human participants (45 CFR 46), but is somewhat more restrictive. Review also must include consideration of local laws, regulations and policies that may apply to the research activity. In Washington, laws that may apply to research include abuse reporting, mandatory disease reporting, and disclosure of HIV testing or treatment for STDs.

The *WSIRB Review Worksheet* provides guidance to reviewers in considering applicable regulations, laws, policies and ethical principles to the review of research proposals. Primary reviewers are required to complete the *WSIRB Review Worksheet* for their assigned proposal and turn it in to the ES/AES at the end of the Board meeting. Other Review Board members are encouraged to use the worksheet as guidance in reviewing proposals.

The following review criteria are carefully considered in the WSIRB review of research proposals:

5.3.1 Study Design and Scientific Merit

The review of research begins with an assessment of the overall scientific merit and the logical and technical soundness of the proposal. The proposal should discuss the relevant literature or describe the context in which the study will occur to provide an adequate conceptual framework. The objectives, research questions and/or hypotheses of the study should be clearly stated, and the proposed methods and study instruments should produce data relevant to the study objectives. Plans for data analysis should be well-defined and likely to produce results related to the study purposes, objectives and hypotheses. The researcher should have appropriate qualifications to conduct the project, or adequate supervision by a qualified professional if the researcher is a student.

5.3.2 Benefits and Risks

A fundamental task in the Board's review of proposals is to balance the anticipated benefits and risks of the research activity. Benefits accruing from research may include direct, personal benefits to the participants, such as increased medical oversight of a condition or disease, or the opportunity to obtain treatments, assessments and/or services not otherwise available. Benefits also include general societal benefits in the form of new scientific or applied knowledge. Compensation to participants is not considered a benefit in the risk/benefit analysis, nor is the fact that participants may find it rewarding to participate. Risks include any research activities that potentially may harm the research participant: psychologically, physically, socially, economically, legally, or otherwise.

Risks may range from physical injury from biomedical or pharmaceutical research, to mere inconvenience from participation in survey research. In assessing risks inherent in a proposal, reviewers will consider both the magnitude and probability of the harm occurring. If the balance between risks and benefits is unfavorable, the Review Board will explore options for reducing risks and/or increasing benefits.

5.3.3 Selection of Participants

Research proposals should clearly define who will be enrolled as subjects in the research and explain why these subjects are being selected. Justification for inclusion and exclusion criteria are reviewed carefully to determine if subject selection is equitable and appropriate for study objectives. Justification must be provided for limiting subject population to an ethnic group or gender. The Review Board will consider whether participants will share benefits in proportion to burdens imposed by the research.

5.3.4 Vulnerable Participants

If vulnerable populations are included, the Review Board will consider whether the research could be done with a non-vulnerable population or whether additional safeguards are necessary to protect vulnerable subjects. Federal regulations for the protection of human subjects (45 CFR 46) require additional protections for the inclusion of pregnant women and fetuses (Subpart B), prisoners (Subpart C), and children (Subpart D) in research. Other vulnerable populations that may require additional safeguards include persons that are decisionally-impaired, disabled, institutionalized, and/or socially or economically disadvantaged.

5.3.5 Participant Recruitment

The Review Board will examine the procedures for identifying, contacting and recruiting potential participants. Generally, researchers should not make first contact with potential participants. If the researcher proposes to identify and sample the study population from confidential state agency records, contact must first be made by agency employees and individuals must be provided, at a minimum, the option of refusing further contact regarding the research. Recruitment procedures must be free of coercion and must present information in a format and language that the intended population can understand.

5.3.6 Informed Consent

The informed consent process must ensure 1) that adequate information is provided, 2) that comprehension is verified, and 3) that participation is voluntary. Reviewers will consider the appropriateness of the individual(s) who will obtain consent, as well as the location and timing of

the consent process. The researcher must provide complete information about the proposed research and the individual's role in the research in an environment and manner that is free of coercion or undue influence and in a format and language that potential subjects can understand. Consent/assent documents must contain all required consent elements, and be written at an appropriate reading level and language for the intended study population.

Research proposals involving vulnerable populations (including pregnant women, fetuses, children, decisionally-impaired, institutionalized, prisoners, socially or economically disadvantaged) merit special consideration to determine whether subjects are capable of understanding the research and providing informed consent, and to minimize the potential for coercion in the consent process. The Review Board must ensure that there are adequate safeguards in place to protect the interests of vulnerable subjects, i.e., requiring a consent witness or subject advocate. Assent to participate in research generally is required from persons who are decisionally-impaired and/or legally incompetent, as well as children less than 18 years of age. In addition, informed consent must be obtained from parents, legal guardians, or family members who may legally provide consent, and, in some cases, from the social worker assigned to potential subjects.

Waivers or alterations of consent requirements may be approved by the Review Board provided the conditions delineated in 45 CFR 46, the HIPAA Privacy Rule, when applicable, and other relevant federal regulations, state statutes and rules, have been documented to the Board's satisfaction. The general requirement for written (i.e., signed) consent can be waived if conditions in 45 CFR 46.117(c) are satisfied. If signed consent is waived, verbal consent (e.g., in the case of telephone surveys) or implicit consent (e.g., in the case of mailed surveys) must be obtained. State laws which allow minors to obtain family planning services, treatment for STDs, outpatient substance abuse treatment and outpatient mental health treatment without parental permission, may help justify waiver of parental permission for participation in research related to these services. However, requirements for waiver of parental permission in 45 CFR 46.408(c) must also be satisfied.

5.3.7 Privacy and Confidentiality

The Review Board will carefully consider possible risks to participant privacy and confidentiality in all phases of the proposed research: sampling, recruitment, consent procedures, proposed methods and setting for data collection, etc. The Review Board may require alterations in the proposed study to minimize privacy and confidentiality risks. Research which may pose special concerns may include surveys or interviews in which sensitive information regarding the subject's personal experiences or behavior is collected, genetics research, and/or research

which collects personal information or physical specimens for possible future use in unspecified research may be retained.

5.4 Procedures: Initial Full Board Review of Research

5.4.1 Pre-review Procedures

Research proposals requiring full Board review are pre-reviewed before being placed on the agenda of a convened meeting of the Review Board. Pre-review is intended to determine if the proposal is complete, responsive to instructions in the application forms, and ready for full Board review with a relatively low chance of approval being deferred. Pre-review is an administrative review process and does not represent an official review by the IRB. The investigator is free to accept or to reject the advice provided in the pre-review. However, the intent of pre-review is to alert the principal investigator to issues which are likely to be raised in the IRB review, and failure to respond to the pre-review issues before the Board meeting could delay approval of the proposed research.

The ES/AES will ask one Board member to serve as the primary reviewer of the proposal and also to participate in the pre-review with the ES/AES. In some instances, a secondary reviewer also will be assigned. An electronic copy of the proposal is emailed to the primary reviewer and a telephone pre-review conference is scheduled within five working days of receipt of the proposal. At the pre-review conference, the ES/AES and the primary reviewer identify issues and concerns that could prevent approval or conditional approval of the proposal in the Board meeting. Within one day of the pre-review conference, the ES/AES sends a *Summary of Pre-Review Issues* by email to the principal investigator with a request to incorporate responses to the issues and/or concerns into a revised research proposal.

Investigators are allowed seven calendar days to submit to the HRRS an electronic copy of the revised research proposal in mark-up text which identifies where the revisions have been made in the proposal. At the same time, the HRRS must receive a clean, original, revised proposal with all required signatures and twenty clean paper copies of the revised proposal for distribution to Review Board members at least one week in advance of the convened meeting.

All investigators are asked to be available by telephone during the time their proposal is being discussed in the meeting. If questions arise that cannot be answered, the ES/AES will contact the investigator and patch him/her into the meeting by telephone conference call.

If a proposal is unusually complicated, or if considerable uncertainty or concerns exist about critical aspects of the research, the investigator may be invited to attend a subsequent Board meeting to provide additional

information or to respond to specific review concerns. Investigators may request to attend initial or subsequent meetings to provide information about their proposal. The investigator must leave the meeting prior to the discussion and disposition vote by the Board.

Review Board members are provided with *Review Worksheets* and the full project application, including the narrative project description, data collection instruments, the proposed informed consent document(s), all recruitment materials, and the justification for waiver(s) of consent, documentation of consent, parental consent, and/or authorization for disclosure of identifiable personal records or protected health information, if applicable. Primary reviewers also are provided with the grant application and the Investigator's Brochure, if they exist for the proposed research.

5.4.2 Board Meeting Review Procedures

WSIRB Rules of Order are followed during full Board meetings. Board members with any conflict of interest with the proposal under review will be expected to abstain from voting. If the conflict is significant (e.g., the Board member is the principal investigator or a member of the research team), the member will be expected to recuse himself/herself from the discussion of the proposal and leave the room.

The primary reviewer presents the proposal beginning with a brief summary of the study design. The primary reviewer will then discuss any questions or concerns based on scientific merit, subject selection and recruitment, vulnerable populations, the informed consent process and documents, any waivers or alterations of informed consent, and issues related to privacy and confidentiality. The primary reviewer will then summarize the risks to subjects in relation to the benefits of the research, and make a motion for disposition of the proposal. When the motion is for approval or conditional approval, the primary reviewer will recommend the appropriate approval period based criteria discussed in Section 5.6.

After a motion is made and seconded, the Chair will recognize other Board members who wish to make comments about the risk/benefit ratio of the proposed research. (Note: consideration of risk/benefit ratios implicitly involves consideration of issues related to the integrity of the study design.) Other members who wish to speak to the same question will be recognized by the Chair in turn. When comments about risk/benefit ratios are concluded, the Chair will ask if any members wish to speak to issues related to recruitment, consent and/or waiver of consent, and will recognize members in turn. Finally, the Chair will ask if any members wish to speak to issues related to general study methods and procedures, data collection instruments and procedures, and language in consent documents. The Chair may then open the floor to general discussion.

After deliberation, the Chair will ask the primary reviewer if he/she wishes to amend or withdraw the motion on the floor. If the primary reviewer withdraws the motion on the floor, he/she will be asked if he/she wishes to introduce a new motion. The Chair will then ask any other members if they wish to amend the motion on the floor. With the assistance of the ES/AES, the Chair will then restate the motion, including any amendments, before the formal vote is taken. Disposition options are listed in Section 4.3.6. Disposition of the proposal is determined by a simple majority vote of members present. The Chair votes only to break a tie. If the motion does not pass, the floor is open to disposition motions introduced by other Board members. The process continues until the Board has approved a disposition motion by a simple majority of members present at the meeting.

5.4.3 Procedures for Reporting Review Findings to Investigators and to Agency Administrators

Following the meeting, the ES/AES will prepare in writing the Board's disposition decision and any remaining review issues and/or required revisions for transmission to the investigator. The primary reviewer, and any other member in attendance at the meeting who asks, will review and comment on draft Board correspondence before it is mailed to the investigator. Board correspondence is mailed to investigators no later than 10 days after a scheduled Board meeting. If a proposal is granted approval or conditional approval, the ES/AES completes the *Documentation of Findings Form* and includes it in the project file. This form is attached to and becomes a part of the minutes of each meeting

If a proposal is <u>not</u> approved at the meeting, investigators must submit a substantive response to the stipulated approval conditions or to the review issues raised during review of his/her proposal <u>within 90 days of the review</u>. The Review Section will email the investigator about two weeks prior to the 90 day deadline to inquire if a response will be submitted. If no response is received, the proposal will be canceled, and the investigator will be required to submit a new research application for review at a convened meeting.

If a proposal is conditionally approved at the meeting, the investigator's response to the Review Board will be reviewed within 5 days of receipt by a Board subcommittee consisting of the Primary Reviewer, the ES/AES, and sometimes the Board Chair. Board members with special expertise in the subject area of the research may be asked to join the subcommittee, and any member in attendance at the meeting may volunteer to participate on the subcommittee. The WSIRB subcommittee generally communicates via telephone conference call.

If the subcommittee documents that the investigator's response satisfies the approval conditions stipulated by the Review Board, an approval letter is drafted for signature by the Executive Secretary or Associate Executive Secretary and by the agency administrator in whose jurisdiction the research will be conducted. The agency administrator will receive copies of the approved proposal, the Review Board's correspondence, the investigator's response(s) to the Review Board, and any other relevant documentation. The agency administrator provides final departmental approval for the commitment of staff and organizational resources needed for the study to be conducted. When the approval letter has been signed by the agency administrator it is returned to the HRRS and then mailed or faxed to the investigator. Copies are sent to agency program managers in units affected by the research, and are filed in the project file.

The final approval letter informs the investigator of the following:

- The approval/anniversary date determined by the date of the Review Board meeting at which the proposal was granted approval or conditional approval.

- The approval period determined by the Review Board at the time of approval. A progress report is required before the anniversary date if the project extends past the approval period.

- That no changes in study purposes, design or methods may be initiated prior to review and approval by the Review Board, except when necessary to eliminate apparent immediate hazards to the subject.

- That adverse events and unanticipated problems involving risks to subjects or others must be reported promptly to the Review Board.

- That study completion requires submission of a final report.

Included with the approval letter will be the following:

- Copies of all Board approved consent and assent forms, recruitment and consent scripts, and contact letters, stamped with the period of approval.

- The *Documentation of Findings* form, which specifies the Board's findings with respect to level of risk, length of approval period, special protections for vulnerable populations, and the approved rationale for waiver of consent or authorization, if applicable.

- A confidentiality agreement, if the research involves disclosure of state agency record information without the consent or authorization of the persons to whom the records pertain.

If action on a proposal is deferred during the meeting due to unresolved issues and concerns or incomplete information, the investigator will be instructed to address the review issues and incorporate them into a revised proposal for review at the next convened meeting of the Review Board. A mark-up electronic copy of the revised proposal will undergo pre-review to determine if it is ready for resubmission to the full Board.

5.5 Procedures: Initial Expedited Review of Research

To qualify for expedited review, a research proposal must incur no more than minimal risk for participants and must involve only one or more of the activities that are listed in Section X of the *Washington State Agency Policy on Protection of Human Research Subjects*. These activities are more restrictive than the federally approved activities for expedited review, and reflect a higher local standard for what can be reviewed through the expedited process.

When discussing research plans with investigators prior to submission of the application for review, HRRS staff generally will be able to determine whether the proposal qualifies for expedited review. Incoming proposal are screened to ensure they meet expedited criteria and that they are reasonably complete, responsive to instructions in the application forms, and ready for review, before they are assigned for review.

If a proposal is eligible for expedited review, the ES/AES will assign one or more Board members to review the proposal. An electronic copy of the proposal is emailed to the primary reviewer and a telephone review conference is scheduled within five working days of receipt of the proposal. Expedited reviewers should use the *Review Worksheets* and apply the same review criteria to proposals as in a full-Board review. Expedited reviewers may exercise all the authorities of the Review Board, and review disposition options are the same as in full Board reviews (See Section 4.3.6), except that proposals may not be disapproved through the expedited process. If expedited reviewers believe that proposal should be disapproved, it will be placed on the agenda for consideration at the next convened meeting of the Review Board.

Disposition decisions in an expedited review are generally achieved through consensus. If two reviewers disagree over the disposition of a proposal, the Chair will become a third reviewer and the majority decision will prevail.

Following the review, the ES/AES will prepare in writing the Board's disposition decision and any remaining review issues and/or required revisions for transmission to the investigator. Investigators can expect to receive Board correspondence within several days of the expedited review. If the proposal is granted approval or conditional approval during the initial expedited review, the

ES/AES completes the *Documentation of Findings Form* and includes it in the project file.

If a proposal is not approved at the expedited review conference, investigators must submit a substantive response to the approval conditions stipulated or review issues raised during review of his/her proposal within 90 days of the review. The Review Section will email the investigator about two weeks prior to the 90 day deadline to inquire if a response will be submitted. If no response is received, the project file will be canceled, and the investigator will be required to submit a new research application for subsequent expedited review.

If a proposal is conditionally approved at the expedited review conference, the investigator should submit a response to the Review Board's approval conditions and an original proposal with all required signatures and four paper copies of the proposal. The investigator's response to the Review Board will be reviewed within 5 days of receipt by the ES/AES. If the ES/AES documents that the investigator's response satisfies the approval conditions stipulated by the Review Board, an approval letter is drafted for signature by the Executive Secretary or Associate Executive Secretary and by the agency administrator in whose jurisdiction the research will be conducted. The approval date for the study is the date of the initial expedited review. Procedures for reporting Review Board findings to investigators and to agency administrators are the same as for full Board reviews.

If action on the proposal is deferred during the expedited review conference due to unresolved issues and concerns or incomplete information, the investigator will be instructed to address the review issues and incorporate them into a mark-up electronic copy of the proposal for review at another expedited review conference. At the same time, the investigator should submit an original revised proposal with all required signatures and four paper copies of the revised proposal. The revised proposal will then be scheduled for another telephone review conference. The approval date for the study is the date of the expedited review conference at which the proposal is either approved or conditionally approved.

5.6 Criteria for Determining Frequency of Continuing Review

During the initial review of the research proposal, the Review Board considers a number of factors in establishing the period of approval for the study. The length of approval in turn establishes the frequency of continuing review. Criteria that are used in making this determination include, but are not limited to, the following:

- The nature of the study;
- The degree of risk involved;
- The vulnerability of the study participant population;

- Evidence of noncompliance with Review Board requirements and/or any applicable policies, laws or regulations.

Investigators are informed of the length of the study approval period for their research in their original approval letter, and in their continuation approval letters, from the Review Board.

5.7 Continuing Review of Research

Principal investigators of ongoing research projects are required to submit progress reports for continuing review at intervals commensurate with the degree of risk posed by the research, but not less than once per year, as determined by the Review Board. Continuing review of research is conducted by the convened Review Board, with recorded vote on the disposition, unless the research is appropriate for expedited review. Generally, if research did not qualify for expedited review at the time of initial review, it will not qualify for expedited review at the time of continuing review until all contacts with subjects are completed.

5.7.1 Submission of Progress Reports

The HRRS Administrative/Training Coordinator notifies investigators by email of the need to submit a progress report for continuation review and approval. Progress reports for research projects are requested at least three weeks in advance of the submission due date for the next meeting. Progress reports eligible for expedited review are reviewed outside the meeting but are placed on the agenda of the convened meeting for information only.

Progress reports must be submitted on the *WSIRB Progress Report Form* available on the HRRS website http://www1.dshs.wa.gov/rda/hrrs/. Progress reports may be submitted electronically by email attachment to wsirb@dshs.wa.gov. Investigators should send a signed, paper copy of the progress report form to the HRRS mailing address listed on our website.

Investigators are required to submit the following information in their progress report:

- The current status of the project in terms of whether recruitment and enrollment is ongoing, whether contacts with subjects is completed, or whether the study involves only use of existing records;

- A general overview of study activities to date;

- Study amendments implemented since the initial review for new studies or the previous continuation review for ongoing projects;

- The number of subjects targeted for enrollment during the entire study; the number approached for participation since the last review, the number of subjects who declined, were ineligible, currently enrolled, and the cumulative total of subjects enrolled to date;

- Any new literature, findings, or other relevant information that may affect study goals, objectives, procedures, and/or risks to participants;

- A description of any adverse events or unanticipated problems, including problems with recruitment, retention, field activities, complaints about research, etc.;

- A summary of remaining study activities to be conducted;

- The estimated study completion date;

- Information on who has access to confidential records for the research;

- Copies of consent documents, if contacts with subjects is ongoing.

Research involving only the secondary use of identifiable records in which no subjects were directly recruited and enrolled are not required to provide information on the numbers of subjects.

Principal investigators must provide documentation of current (within three years) training in the protection of human research subjects before continuation approval for their research will be extended.

For completed studies, researchers also must submit a copy of a final report. If the study required a Confidentiality Agreement for disclosure of identifiable records, investigators must provide written assurance that all terms of the Agreement have been satisfied. Usually this requires written certification that all data elements that could directly or indirectly identify individuals have been permanently removed and destroyed.

5.7.2 Procedures for Continuing Review

When progress reports arrive in the HRRS, the Administrative/Training Coordinator screens each for completeness, reviews the corresponding project file, and evaluates the project's conformity with Board approved procedures. Consent forms submitted with the progress forms are compared to Board approved forms and deviations from the approved

forms are noted. The investigator's training in human subjects protection is verified to determine it has been completed within the last three years. Any deviations from Board approved procedures are noted in a report provided to the ES/AES. If deviations from approved procedures are noted and/or if training is out of date, the Administrative/Training Coordinator will contact investigators and work with them to submit information necessary to bring the project back into compliance.

Following initial review by the Administrative/Training Coordinator, the ES/AES conduct their own review of the progress report and project file prior to the scheduled Board meeting. Any information needed to allow continuation approval in the meeting is solicited by the ES/AES directly from the investigator prior to the meeting. As necessary, the ES/AES consults with the primary reviewer prior to the meeting to provide feedback regarding recruitment and consent documents, and any issues that arose during review of the project file, and or discussions with the investigator.

Full Board Continuing Review: Progress reports for research reviewed by the full Board during initial review are reviewed by the full Board for continuing review, unless the research is permanently closed to the enrollment of new subjects and all contacts with subjects for research purposes have been completed. Full Board continuing review generally is conducted by the original primary reviewer (if available) or by the ES/AES. The primary reviewer and all review Board members receive a copy of the complete progress report. The ES/AES and primary reviewers have access to the project file, and have copies of all recruitment and consent documents and published articles submitted with the progress report.

The primary reviewer presents the progress report to the WSIRB at a convened meeting prior to the anniversary date. The primary reviewer provides a brief overview of the research and progress made over the past year, the number of subjects accrued, a summary of any recent literature, any interim findings, and amendments or modifications to the research since the last review. Unanticipated problems and/or adverse events or concerns regarding conduct of the research are discussed, and remaining study activities are noted. Following presentation, the primary reviewer makes a motion regarding continuation approval and the Review Board votes on disposition. The motion will include recommendations for revising the consent form based on changes in risks, and changes in the period of approval, as applicable.

Expedited Continuing Review: Progress reports for research reviewed under expedited review authority during initial review generally are reviewed under expedited authority for continuing review provided there have been no serious or unanticipated events, or changes in procedures that could increase risk to participants. Certain categories of research

originally reviewed by the full Board are eligible for expedited review if they meet criteria in the *Washington State Agency Policy…*, Section X, Research Categories 12 and 13. Expedited continuing review is conducted by the ES/AES prior to the project's anniversary date. Progress reports reviewed under expedited review are included in the next Review Board meeting distribution materials and listed on the meeting agenda for informational purposes. Any Review Board member who has questions about a progress report eligible for expedited review should contact the HRRS prior to the meeting, but also may raise issues or questions in the meeting.

Continuing Review Dispositions: Disposition options for continuing review of research parallel the disposition options for initial review, listed in Section 4.3.6. However, as research undergoing continuing review already have an approval period established with an anniversary date at which approval expires, the implications of various dispositions are different than during initial review, as follows:

- Projects that receive conditional continuation approval must receive final continuation approval prior to expiration of the approval period; if a project fails to receive final continuation approval before the expiration of the approval period all study activities involving human subjects and/or use of confidential records must cease immediately. The only exception is if continued subject participation in the research is necessary for the subject's safety. After study approval expires, the investigator has thirty days to reinstate study approval or approval is permanently canceled.

- Projects in which continuation approval is deferred must receive final continuation approval prior to expiration of the approval period, or all study activities involving human subjects and/or use of confidential records must cease immediately. The only exception is if continued subject participation in the research is necessary for the subject's safety. If the continuation approval must be extended by the full Board, the investigator's response to the review issues will be considered at the next meeting; hence, the approval period will expire prior to continuation approval being extended. After study approval expires, the investigator has thirty days to reinstate study approval or approval is permanently canceled.

- In rare instances, approval for conducting the research may be suspended or rescinded during the continuation review process. While approval may be suspended under expedited authority, approval can be rescinded only by action of the full Review Board. While this disposition results in the research approval being

permanently canceled, the investigator is free to submit a new proposal for consideration at a later date.

Reporting Continuing Review Findings to investigators: Investigators are informed by letter of the Review Board's decision regarding continuation prior to the project's anniversary date. Once continuation approval conditions or review issues have been resolved, researchers will receive a continuation approval letter. For projects involving direct contact with human subjects, continuation approval letters will be accompanied with the contact letter(s), consent form(s), and telephone script(s) stamped "approved" through the next project anniversary date. These approved forms must be used for all recruitment and enrollment activities.

5.7.3 Expiration of Study Approval

Failure of the investigator to submit a progress report, respond to conditions or review issues required by the Board during the continuation review, and/or to provide documentation of current training in the protection of human participants before the project anniversary date will result in expiration of study approval. If study approval expires, all research activities, including contacts with human subjects and/or use of any identifiable data, must be suspended. The only exception is if continued subject participation in research is necessary for the subject's safety. In that event, the ES/AES must be notified immediately.

Review Board approval for an expired study must be reinstated no later than 30 days from the expiration date. On the expiration date, the ES/AES sends the investigator a letter directing that all research activities be suspended immediately, except if continued subject participation in study activities is necessary for the subject's safety. The letter also explains the consequences of failing to reinstate study approval within 30 days. If all materials needed to reinstate continuation approval are not received within 30 days, Review Board approval will be permanently canceled due to non-compliance with federal regulations (45 CFR 46) and *Washington State Agency Policy*. The following will then occur:

- The Review Board will notify the head of the investigator's department or division, the IRB at the investigator's home institution, and the investigator's funding agency of this action;

- If it is federally supported research, the federal Office of Human Research Protections will be notified of this action;

- The investigator will be required to immediately return all copies of identifiable personal record information disclosed for research purposes. Failure to immediately return identifiable personal record information is a violation of Washington State law (RCW

42.48) and will be reported to the Attorney General's Office for further action;

- Approval to continue the canceled research will require submission of a new application for review and approval by the WSIRB.

5.7.4 Independent Verification that No Material Changes Have Occurred Since the Previous Review

The Review Board may determine that a project needs verification from sources other than the investigator that the project is being conducted in compliance with procedures approved by the Review Board and that no material changes have occurred since the previous review. Factors considered by the Review Board in determining the need for such verification include, but are not limited to:

- Projects conducted by researchers who previously have failed to comply with the requirements or determinations of the Review Board and/or applicable laws and regulations.

- Complex projects involving unusual levels or types of risks to participants.

- Projects where concern about possible material changes occurring without Review Board approval have been raised based upon information provided in progress reports or from other sources.

Outside verification may be obtained 1) by conducting inquiries, or site visits with or without formal audits of study procedures, to collect information to report back to the Review Board; or 2) by having third parties observe the consent process and conduct of the research. As necessary and/or appropriate, this determination will be made by the Review Board at any time during the approval period of a project, or prior to extending continuation approval for the research. If necessary to address immediate concerns about non compliance and/or risks to subjects, this decision may be made by the ES/AES and applicable WSIRB Chair. Written notice of intent to conduct a site visit which may include an audit of study activities, or to have third parties observe the consent process, will be provided to the investigator no less than 48 hours before the planned site visit. Such written notice will include an explanation of the reasons for the site visit and an outline of the study procedures and materials that will be reviewed.

5.8 Study Amendments

Investigators must request WSIRB review and approval of all proposed changes in approved research. Such requests are submitted for review as a study amendment. No changes to an approved protocol may be initiated without prior

approval of the Review Board, except when necessary to eliminate immediate hazards to participants.

5.8.1 What Requires Review

Study amendments requiring review include, but are not limited to:

- Revisions to study methodology, including study eligibility;
- Addition of new study sites;
- Revisions to recruitment materials or methods;
- Revisions to contact and consent procedures;
- Revisions to consent form;
- Implementation of additional instruments, or revisions to approved instruments;
- Requests for additional department records;
- Contact with participants for research purposes when all previous study activities were restricted to records and datasets;
- Requests to link study datasets to additional datasets not previously approved by the Review Board.

5.8.2 Submission of Study Amendments

Study amendments must be submitted on the *Study Amendment Form* available at: http://www1.dshs.wa.gov/rda/hrrs/. Study amendments may be submitted electronically by email to wsirb@dshs.wa.gov. Alternatively, investigators may send a paper copy of the study amendment form to the HRRS mailing address listed on our website. Unless otherwise instructed by the HRRS staff, multiple copies are not required.

A study amendment request should clearly indicate the proposed revision(s) and provide a rationale indicating how the proposed amendment relates to overall study objectives and the research questions under analysis. The investigator also should describe any problems with current approved procedures, study recruitment, or other issues that may necessitate the proposed revision(s). Any proposed instruments, protocols, and other documents to be used if the amendment is approved should be attached to the *Study Amendment Form*.

5.8.3 Procedures for Reviewing Study Amendments

Upon receipt of a request for a study amendment, the ES/AES will screen the proposed revision(s) and determine the appropriate level of review. Minor changes in previously approved research during the period for which approval is authorized qualify for expedited review. Examples include minor revisions to consent forms, minor changes in study incentives, requests for additional identifiable records, or minor changes to study instruments. In general, study amendments are reviewed under expedited review procedures if the proposal was eligible for expedited review at initial review. Expedited reviews are conducted by the ES/AES, who may request the involvement of the primary reviewer or Board Chair, as appropriate.

Study amendments for projects that were reviewed by the full Board at initial review may require full Board review. If a proposed amendment introduces procedures or methods that may increase risks to participants, if it involves a significant change to currently approved procedures, or if it incorporates a vulnerable study population, the study amendment will be forwarded to the full Board for review at a convened meeting. Study amendments reviewed by the full Board are presented by the primary reviewer or by the ES/AES if the primary reviewer is not available. Voting on study amendment dispositions follow the same procedures as for the initial and continuing review of research.

Investigators are informed by letter of the Review Board's decision regarding review of a study amendment. Once approval conditions or review issues have been resolved, the investigator will receive a study amendment approval letter. If the study amendment requires changes in consent documents, the newly approved consent documents stamped with the period of approval will be enclosed with the approval letter. If the study amendment requires changes in the confidentiality agreement which authorizes disclosure of individually identifiable personal record information, an addendum to the agreement for signature by the investigator will be enclosed with the approval letter. When signed by the appropriate agency administrator the addendum authorizes disclosure of the additional confidential record information needed for the research. A copy of the signed addendum is sent to the investigator and to the program manager responsible for disclosing the data to the investigator.

5.8.4 Procedures for Ensuring Prompt Reporting to the WSIRB of Proposed Changes in a Research Activity

Investigators are informed at multiple points during the ongoing review process of the importance of promptly reporting proposed changes to approved research activities to the WSIRB:

- Investigators are informed in the initial approval letter that changes in study purposes, design or methods may not be initiated prior to review and approval by the Review Board, except when necessary to eliminate apparent immediate hazards to subjects.

- Investigators not affiliated with these Washington State Agencies are required to complete and sign an *Unaffiliated Investigator Agreement* which stipulates in part that investigators will report promptly any proposed changes in the research conducted under the Agreement;

- The WSIRB *Progress Report Form* and the *Study Amendment Form* include a statement the investigator must sign which documents his/her responsibility to report to the Review Board any study modifications and that no modifications will be put into effect without prior WSIRB approval;

- During continuation reviews and reviews of study amendments, HRRS staff routinely compare submitted forms with project files to determine that changes in approved study activities have not occurred without prior review and approval by the WSIRB.

5.9 Adverse Events and/or Unanticipated Problems Involving Risks to Subjects or Others

Investigators must promptly report adverse events and unanticipated problems that involve risks to subjects or others to the WSIRB. The promptness of the report and the level of review depends on a number of factors which include, but are not limited to, the following:

- The seriousness of the adverse event or unanticipated problem;

- Whether the adverse event is described in the protocol and consent form;

- Whether the adverse event or unanticipated problem is related to study procedures;

- Whether the adverse event or unanticipated problem occurred at a study site in the jurisdiction of the WSIRB.

5.9.1 Procedures for Reporting Adverse Events and/or Unanticipated Problems Involving Risks to Subjects or Others

Reports of adverse events and/or unanticipated problems must be submitted on the *WSIRB Adverse Events/Unanticipated Problems Form* available at: http:///www1.dshs.wa.gov/rda/hrrs/.

Adverse events that may *reasonably be expected* to arise as a result of research procedures should be described in the consent form and do not need to be reported to the Review Board on an individual basis. However, the incidence of these expected adverse events must be reported in the progress report submitted for continuation approval.

Any *serious or unexpected* adverse reactions to drugs and/or medical procedures, or to the administration of psychological assessments or instruments designed to collect personal or sensitive information from subjects, must be promptly reported to the WSIRB. Any unanticipated problems that involve risks to subjects or others resulting from any aspect of the research must be promptly reported to the WSIRB.

For *serious or unexpected* adverse events and unanticipated problems involving risks to subjects and others, researchers should follow the following reporting guidelines:

- Expected adverse events occurring with greater frequency or at a higher level of severity than anticipated: Investigators should submit a *WSIRB Adverse Events/Unanticipated Problems Form* to HRRS as soon as the finding is noted. Forms should be submitted electronically to wsirb@dshs.wa.gov.

- Serious or unexpected adverse events or unanticipated problems involving risks to subjects or others: Investigators must submit a *WSIRB Adverse Events/ Unanticipated Problems Form* to HRRS within 48 hours of the event. Forms should be submitted electronically to wsirb@dshs.wa.gov.

5.9.2 Procedures for Reviewing Adverse Events and/or Unanticipated Problems Involving Risks to Subjects or Others

The ES/AES reviews all *Adverse Events/ Unanticipated Problems Forms* as they are submitted to determine if the event and/or problem is of sufficient importance to require review by a subcommittee comprised of the ES/AES, primary reviewer and Board Chair. If so, and if the reported event appears to be related to study procedures, this subcommittee reviews the consent form language describing the risks to evaluate possible revisions and whether participants already enrolled in the research should be appropriately advised. The subcommittee may request reports by the coordinating institution's Data and Safety Monitoring Board (for multi-site clinical research), or request additional information from the investigator.

All adverse events and unanticipated problems are reported to the full Board and documented in the minutes of the meeting. The full Board may determine that additional action needs to be taken in response to the report. Additional action could include, but is not limited to, requiring

additional revisions in the consent form, advising or requiring that the study be modified to reduce risks to subjects, or rescinding study approval if the risks are determined to outweigh anticipated benefits of the research.

Documentation of all reports of adverse events and/or unanticipated problems involving risks to subjects and others, and any action taken by the subcommittee and/or the Review Board are placed in the project file. If the Review Board has serious concerns about the research and safety and welfare of subjects, the ES/AES will inform the investigator, his/her home institution IRB, the coordinating center IRB and/or the funding agency, and OHRP, in writing.

5.9.3 Procedures for Ensuring Prompt Reporting to the WSIRB of Any Adverse Events or Unanticipated Problems Involving Risks to Subjects or Others

Investigators are informed at multiple points during the ongoing review process of the importance of promptly reporting any adverse events and/or unanticipated problems involving risks to subjects or others to the WSIRB:

- Investigators are informed in the initial approval letter that adverse events and/or unanticipated problems involving risks to subjects or others must be promptly reported to the WSIRB.

- Investigators not affiliated with these Washington State Agencies are required to complete and sign an *Unaffiliated Investigator Agreement* which stipulates in part that investigators will report immediately to the WSIRB any unanticipated problems involving risks to subjects or others in the research conducted under the Agreement;

- The WSIRB *Progress Report Form* and the *Study Amendment Form* include a statement the investigator must sign which documents his/her responsibility to report to the Review Board any emergent problems, serious adverse events or reactions to the WSIRB.

5.10 Noncompliance Procedures

Noncompliance with Board approved procedures may involve relatively minor or technical violations which result from inadvertent errors, inattention to detail or inadequate training and supervision of research staff. Noncompliance may also involve more serious violations of WSIRB approved procedures which pose tangible risks to subjects and/or violations of their rights and welfare. Violations of WSIRB approved procedures for protecting the confidentiality of individually identifiable personal record information disclosed for research frequently result in

violations of state or federal laws under which such information is used or disclosed, and will always be considered as serious noncompliance.

WSIRB procedures for responding to investigator noncompliance are based on the seriousness of the violation, the frequency of the violations, and any history of violations the investigator may have:

5.10.1 Minor Noncompliance

If the noncompliance is not serious and appears to be inadvertent, and if the investigator does not have a history of noncompliance, the ES/AES will respond to the noncompliance by communicating with the investigator and attempting to correct the situation through a formal or informal educational intervention. The investigator may be asked to complete continuing education in the protection of human subjects, or may be asked to propose a corrective action plan to the Review Board. The Review Board will be informed of the noncompliance and the action taken by the ES/AES to correct the situation.

5.10.2 Serious Noncompliance

If noncompliance results in tangible risks to subjects and/or violation of their rights and welfare, or if it involves violations of state or federal laws, the ES/AES, in consultation with the Chair of the applicable Review Board, will inform the investigator in writing of the nature of the noncompliance and the steps that must be implemented to correct the noncompliance. The noncompliance will be placed on the agenda of the next Review Board meeting for consideration of whether additional steps should be taken to correct the noncompliance. The full Board may adopt a corrective action plan which includes, but is not limited to, an educational intervention and submission of additional documentation explaining how and why the noncompliance occurred and how it will be prevented in the future. The investigator's immediate supervisor, the IRB in the investigator's home institution, and the Assistant Secretary or Division Director of the program area in which the research is being conducted will be informed of the noncompliance and the Review Board's action. The funding agency and the Attorney General's Office may be informed, depending on the seriousness of the noncompliance, and whether any state or federal laws have been violated.

5.10.3 Serious and Continuing Noncompliance

If an investigator exhibits serious and continuing noncompliance with Board approved procedures the ES/AES will present a report to the full Board with a recommendation that project approval be suspended or permanently canceled.

If project approval is suspended, the Review Board will stipulate the conditions for reinstatement of WSIRB approval or the review issues the investigator must respond to before reinstatement will be considered by the Review Board. The investigator's response to the re-approval conditions may be reviewed, and study approval reinstated, by a Board subcommittee. The investigator's response to review issues must be considered at a scheduled Board meeting, after which the Board will vote either to reinstate or to permanently cancel study approval.

If a project approval is permanently canceled by vote of the full Board due to serious and continuing noncompliance, the following will occur:

- The Review Board will notify the head of the investigator's department or division, the IRB at the investigator's home institution, and the investigator's funding agency of this action;

- If it is federally supported research, the federal Office of Human Research Protections will be notified of this action;

- The investigator will be required to immediately return all copies of identifiable personal record information disclosed for research purposes. Failure to immediately return identifiable personal record information is a violation of Washington State law (RCW 42.48) and will be reported to the Attorney General's Office for further action;

5.10.4 Noncompliance Prior to Initial Study Approval

In some instances, serious noncompliance with *Washington State Agency Policy*… and/or violations of state or federal law may be detected during the initial review of a research proposal. Detection of serious noncompliance or violation of law during the initial review of a research proposal is sufficient grounds for disapproval of the research proposal. If serious noncompliance or violation of law is discovered during the initial expedited review of a proposal, the ES/AES, Board Chair or primary reviewer may make a motion for disapproval of the proposal at the next scheduled meeting of the Review Board.

5.11 Study Completion/Cancellation

Upon completion of a research project the Principal Investigator is required to submit a final project report. The following documents will be accepted as the required final report: a copy of a published article based on the research; a report prepared for the institution that funded or sponsored the research; a thesis or dissertation based on the research. The investigator should consult with HRRS staff if there is a question about what will be accepted as the final project report.

If the project required a Confidentiality Agreement for the disclosure of individually identifiable personal record information, the investigator must meet all requirements in the Agreement before the study file can be closed. At a minimum, this requires the investigator to certify in writing the destruction of all data elements that could directly or indirectly identify individuals whose records were disclosed for the research as soon as the purposes of the research have been accomplished.

For research that involves collecting primary research data from subjects, the investigator will be asked to certify that all terms and conditions in the study consent and/or assent forms have been fulfilled, including that identifiers have been permanently removed from study records and destroyed. If identifiers will not be destroyed until several years after the project file is closed, the investigator will be asked to certify that the identifiers will be destroyed on the specified date.

When the final report and written assurance that identifiers have been destroyed are received by HRRS, the principal investigator is informed by letter that the requirements to the WSIRB have been completed and the project file is closed.